Medical Policy

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***Current Policy Effective Date: 7/1/25**
(See policy history boxes for previous effective dates)

Title: Bariatric Surgery (Gastric Surgery for Morbid Obesity)

Description/Background

BARIATRIC SURGERY

Bariatric surgery is performed to treat obesity and obesity-related comorbid conditions. The first treatment of obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few individuals with obesity can reduce and control weight through diet and exercise. Most patients find it difficult to comply with these lifestyle modifications on a long-term basis. When conservative measures fail, some patients may consider surgical approaches.

Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Several gastric bands for use in bariatric surgery have received FDA-approval through the premarket approval process and are summarized in Table 1 (FDA Product Code: LTI):

Table 1: FDA-Approved Bariatric Surgery Devices

Device	Manufacturer	PMA Date	Labeled Indications
Obalon™ intragastric balloon system	Obalon Therapeutics, Inc.	Sept 2016	For use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon is encased in a capsule. The capsule is swallowed and begins to dissolve after exposure to fluids in the stomach. After verification of capsule placement in the stomach, the balloon is filled with a gas mixture. Up to 3 balloons can be used during the 6 mo treatment period.
AspireAssist System®	Aspire Bariatrics	Jun 2016	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults >22 y, with a BMI of 35.0 to 55.0 kg/m^2 and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy.
ORBERA® intragastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30 to 40 kg/m^2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
LAP-BAND Adjustable Gastric Banding System	Apollo Endosurgery (original applicant: Allergan)	Apr 2010	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m^2 or a BMI of at least 30 kg/m^2 with ≥1 severe comorbid conditions who have failed more conservative weight-reduction alternatives (eg, supervised diet, exercise, behavior modification programs).
REALIZE Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m^2, or a BMI of at least 35 kg/m^2 with ≥1 comorbid conditions, or those who are ≥45.4 kg over their estimated ideal weight. Indicated for use only in morbidly obese adults who have failed more conservative weight-reduction alternatives (eg, supervised diet, exercise, behavior modification programs).

BMI: body mass index: FDA: food and drug administration; PMA: premarket approval.

In February 2017, the FDA issued a letter to health care providers discussing the potential risks with liquid-filled intragastric balloons in response to reports of 2 types of adverse events related to the balloons. Several dozen reports concerned spontaneous overinflation of the balloons, which caused pain, swelling, and vomiting. A second set of adverse reports indicated that acute pancreatitis developed in several patients due to compression of gastrointestinal structures. These reports involved both ReShape (no longer marketed in the US) and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of 5 unanticipated deaths occurring from 2016 through the time of the letter, due to intragastric balloons. The FDA recommended close monitoring of patients receiving these devices. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S.

In April 2020, the FDA provided an update on risks and continued to recommend that healthcare providers "instruct patients about the symptoms of life-threatening complications such as balloon deflation, gastrointestinal obstruction, and gastric and esophageal perforation

and monitor patients closely during the entire duration of treatment for potential complications, including acute pancreatitis, spontaneous hyperinflation, and other potentially life-threatening complications."

Esophagogastroduodenoscopy
Esophagogastroduodenoscopy (EGD) is useful for detecting conditions that may contraindicate bariatric surgery, such as malignancies. It assists in planning the appropriate bariatric procedure by identifying other gastrointestinal conditions like large hiatus hernia and peptic ulcer, which could impact surgery. EGD also detects conditions needing preoperative treatment, such as Helicobacter pylori infection. Moreover, endoscopy provides an anatomical assessment of the distal stomach, which becomes inaccessible after specific bariatric procedures.

Medical Policy Statement

Laparoscopic and open gastric restrictive procedures including but not limited to Roux-en-Y gastric bypass, sleeve gastrectomy, biliopancreatic diversion with duodenal switch, single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S), stomach intestine pylorus sparing surgery (SIPS), and adjustable gastric band have been established. They are considered useful therapeutic options when specified criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions:

Single anastomosis duodenoileal bypass with sleeve gastrectomy **(SADI-S)**, and stomach intestine pylorus sparing surgery **(SIPS)** are considered established when the following criteria are met:

The individual has:
- Extremely high BMI (40-60 kg/m2); **AND**
- Low incidence of reflux (for individuals with Barrett's esophagitis or gastroesophageal reflux, the gold standard is Roux-en-Y gastric bypass); **AND**
- Multiple comorbidities (e.g., DM and HTN); **OR**
- Requirement of non-steroidal anti-inflammatory drug therapy for example knee or hip osteoarthritis**.**

Other surgical procedures are considered established when the following criteria are met:

The individual has:
- A BMI of ≥ 40 kg/m2 (class 3) (BMI ≥ 37.5 kg/m2 in the Asian population*) **OR**

- A BMI of ≥35 to 39.9 kg/m2 (class 2) (BMI ≥ 32.5 kg/m2 in the Asian population*) with **one** or more co-morbid conditions including, but not limited to:
  - Degenerative joint disease (including degenerative disc disease)
  - Hypertension
  - Hyperlipidemia, coronary artery disease
  - Presence of other atherosclerotic diseases
  - Sleep apnea
  - Congestive heart failure

  OR

- A BMI of ≥ 30 to 34.9 kg/m2 (class 1) with type 2 diabetes (BMI ≥ 27.5 kg/m2 in the Asian population*).

ADDITIONAL CRITERIA FOR ALL BARIATRIC SURGICAL OPTIONS INCLUDE THE FOLLOWING:

- All individuals meeting one age requirement below:
  - 18 to 60 years of age with conditions above; **OR**
  - Individuals above 60 years of age may be considered if it is documented in the medical record that the individual's physiologic age and co-morbid condition(s) result in a positive risk/benefit ratio; **OR**
  - Criteria for bariatric surgery for individuals younger than 18 years of age are similar: 1) BMI ≥40 kg/m2 (or 140% of the 95th percentile for age and sex, whichever is lower); 2) BMI ≥35 kg/m2 (or 120% of the 95th percentile for age and sex, whichever is lower) with clinically significant comorbidities; and should include documentation that the primary care physician has addressed the risk of surgery on future growth, the patient's maturity level and the patient's ability to understand the procedure and comply with postoperative instructions, as well as the adequacy of family support.
- When evaluating an individual of the Asian population* clinical obesity is defined as a BMI of ≥ 25 kg/m2 (see NICE guideline in supplemental section).
- The individual has undergone multidisciplinary evaluation by an established bariatric treatment program to include medical, nutritional and mental health evaluations to determine ultimate candidacy for bariatric surgery. Such an evaluation should include an assessment of the patient's likely ability and willingness to cooperate effectively with a rigorous post-operative program. This should include documentation of past participation in a non-surgical weight loss program. Documentation of a non-surgical weight loss program is waived for super morbidly obese individuals who have a BMI ≥50. Documentation that the individual has weight related complications, defined as conditions caused by or exacerbated by excess adiposity.
- The non-surgical program participation and multi-disciplinary evaluation must have occurred within 4 years of the date of surgery.
- A psychological evaluation must be performed as a pre-surgical assessment by a contracted mental health professional in order to establish the patient's emotional stability, ability to comprehend the risk of surgery and to give informed consent, and ability to cope with expected post-surgical lifestyle changes and limitations. Such psychological consultations may include one unit total of psychological testing for purposes of personality assessment (e.g., the MMPI-2 or adolescent version, the MMPI-A).

- In cases where a revision of the original procedure is planned because of failure due to anatomic or technical reasons (e.g., obstruction, staple dehiscence, etc.), or excessive weight loss of 20% or more *below* ideal body weight, the revision is determined to be medically appropriate without consideration of the initial preoperative criteria. The medical records should include documentation of:
    - The date and type of the previous procedure
    - The factor(s) that precipitated the failure and/or the nature of the complications from the previous procedure that mandate (necessitate) the takedown
- If the indication for the revision is a weight gain OR a failure of the patient to lose a desired amount of weight DUE TO PATIENT NON-ADHERENCE, then the patient must re-qualify for the subsequent procedure and meet all of the initial preoperative criteria.
- Revision surgery to address severe gastroesophageal reflux disease refractory to medical treatment is considered medically appropriate.

*Asian population: According to the (United States Census Bureau, 2012)[150]. Refers to a person having origins from the Far East, Southeast Asia, or the Indian subcontinent (e.g., Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam).

Exclusions:

The following surgical procedures are considered experimental/investigational because their safety and/or effectiveness have not been proven:

- Loop gastric bypass gastroplasty using a Billroth II type of anastomosis, also known as mini gastric bypass
- Biliopancreatic bypass without duodenal switch
- Long-limb gastric bypass procedure (i.e., >150 cm)
- Stomach stapling (Vertical banded gastroplasty)
- Endoscopic/endoluminal procedures (including but not limited to insertion of the StomaphyX™ device, use of the Overstitch device, insertion of a gastric balloon, endoscopic gastroplasty, intragastric balloons, aspiration therapy device or use of an endoscopically placed duodenojejunal sleeve) as a primary bariatric procedure or as a revision procedure, (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches).
- Any bariatric surgery for individuals with type 2 diabetes who have a BMI of less than 30 or in the Asian population who have a BMI less than 27.5 kg/m2.
- Laparoscopic gastric plication
- Vagus nerve blocking (see separate policy, “Vagus Nerve Blocking for Morbid Obesity.”
- Bariatric surgery for pre-adolescents
- Natural Orifice Transluminal Endoscopic Surgery (NOTES™)
- Two-stage bariatric surgery procedures (e.g., SG as initial procedure followed by BPD at a later time)
- The routine use of esophagogastroduodenoscopy with bariatric surgery.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

43644	43645	43770	43771	43772	43773
43774	43775	43843	43845	43846	43847

43848	43886	43887	43888	43999	44130
96130	96131	96136	96137	96138	96139
S2083					

Other codes (investigational, not medically necessary, etc.):

43290	43291	43842	43999*	96146	C9784
C9785	0813T				

**When used to indicate any of the following procedures:*

- *Loop gastric bypass gastroplasty - also known as mini-gastric bypass*
- *Stomach stapling*
- *Endoscopic procedures to treat weight gain after bariatric surgery*
- *Natural Orifice Transluminal Endoscopic Surgery (NOTES™)*

Note: The code 43842 VBG was moved from covered/EST to excluded. This code remains payable in the system but the code is considered obsolete. The cost and effort of changing the system is not warranted.

Rationale

Bariatric Surgery in Adults With Obesity

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Esophagogastroduodenoscopy with Bariatric Surgery

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Bariatric Surgery in Adults With Obesity

Clinical Context and Therapy Purpose
The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is adults with a diagnosis of obesity.

Diagnosis is based on body mass index (BMI) plus clinical judgment. Clinicians are advised to consider age, gender, ethnicity, fluid status, and muscularity when evaluating individuals for weight management. Classification of overweight and obesity and associated risk of comorbidities is shown in Table 2. Lower BMI thresholds are recommended to a person having origins from the Far East, Southeast Asia, or the Indian subcontinent (e.g., Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam).[150]

Table 2. Overweight and Obesity Classification

Classification	Body Mass Index (kg/m^2)	Comorbidity Risk
Overweight	25.0-29.9	Increased
Class 1 obesity	30-34.9	Moderate
Class 2 obesity	35-39.9	Severe
Class 3 obesity	≥40	Very severe

Weight-related comorbidities are conditions caused by or exacerbated by excess weight. Clinical practice guidelines include a wide range of these conditions:

- Asthma
- Cardiovascular disease
- Certain types of cancer (e.g., colorectal cancer)
- Type 2 diabetes
- Dyslipidemia
- GERD
- Hypertension

- Infertility
- Male hypogonadism
- Mental health (depression)
- Metabolic syndrome
- Nonalcoholic fatty liver disease (nonalcoholic fatty liver and nonalcoholic steatohepatitis)
- Obstructive sleep apnea
- Osteoarthritis
- Polycystic ovarian syndrome
- Prediabetes
- Stroke
- Urinary stress incontinence

Interventions

The therapy being considered is any bariatric surgery procedure.

- **Open Gastric Bypass (gastric restrictive procedure with gastric bypass, with short-limb Roux-en-Y gastroenterostomy) (CPT code 43846)**
  The original gastric bypass surgeries were based on the observation that post-gastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant "dumping syndrome," in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in "sweet eaters." Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there may be more metabolic complications compared with other gastric restrictive procedures, including iron deficiency anemia, vitamin deficiency and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the "blind" bypassed portion of the stomach. Gastric bypass may be performed with either an open or a laparoscopic technique.

  Note: In 2005, the CPT code 43846 was revised to indicate that the short limb must be 150 cm or less, compared to the previous 100 cm. This change reflects the common practice in which the alimentary (i.e., jejunal limb) of a gastric bypass has been lengthened to 150 cm. This length also serves to distinguish a standard gastric bypass with a very long or very, very long gastric bypass, as discussed further here.

- **Laparoscopic Gastric Bypass (CPT code 43644)**
  This code essentially describes the same procedure as open gastric bypass but performed laparoscopically.

- **Open or Laparoscopic Sleeve Gastrectomy (CPT code 43775)**
  A sleeve gastrectomy is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome

(overly rapid transport of food through stomach into intestines) that is seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a two-stage procedure for very high-risk patients. Weight loss following sleeve gastrectomy may improve a patient's overall medical status, and thus reduce the risk of a subsequent more extensive malabsorptive procedure, such as biliopancreatic diversion.

- **Open or Laparoscopic Biliopancreatic Diversion with Duodenal Switch (CPT code 43845)**
  CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is a variation of the biliopancreatic bypass described above. In this procedure, instead of performing a distal gastrectomy, a "sleeve" gastrectomy is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the biliopancreatic bypass, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum. The sleeve gastrectomy also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the procedure is similar to that of the biliopancreatic bypass i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

- **Open or Laparoscopic Biliopancreatic Diversion (also known as the Scopinaro procedure) (CPT code 43847)**
  Biliopancreatic diversion (BPD) procedure, developed and used extensively in Italy, was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many of the complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPD consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components:
  - A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
  - A 200 cm long "alimentary tract" consists of 200 cm of ileum connecting the stomach to a common distal segment.
  - A 300 to 400 cm "biliary tract," which connects the duodenum, jejunum and remaining ileum to the common distal segment.
  - A 50 to 100 cm "common tract," where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel (i.e., creating selective malabsorption). The length of the common segment will influence the degree of malabsorption.

  Because of the high incidence of cholelithiasis associated with the procedure, a patient typically will undergo an associated cholecystectomy.

  Many potential metabolic complications are related to biliopancreatic diversion, including most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition.

In addition, there have been several case reports of liver failure resulting in death or liver transplant.

- **Laparoscopic Adjustable Gastric Banding (CPT code 43770)**
  Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple.

  Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe. Two such devices are approved by the U.S. Food and Drug Administration (FDA) for marketing in the U.S. The first such device that received FDA approval was the LAP-BAND (original applicant, Allergan Inc., BioEnterics, Carpinteria, CA; sold to Apollo Endosurgery Inc., Austin, TX, in 2013). The labeled indications for this device are as follows:

  "The LAP-BAND system is indicated for use in weight reduction for severely obese patients with a body mass index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives."

  In 2011, FDA-labeled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 with at least one obesity-related comorbid condition.

  A second adjustable gastric banding device was approved by the FDA through the Premarket Approval (PMA) process in September 2007, the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are as listed below:

  “The [REALIZE] device is indicated for weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m2, or a BMI of at least 35 kg/m2 with one or more comorbid conditions. The band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs.”

- **Mini Gastric Bypass (no specific CPT code)**
  In this variant of the gastric bypass, using a laparoscopic approach, the stomach is segmented as in a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure. The unique aspect of this procedure is not based on its laparoscopic approach, but rather the type of anastomosis used. It should also be noted that CPT code 43846 explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass.

- **Endoluminal (also called endosurgical, endoscopic, or natural orifice) bariatric procedures (no specific CPT code)**
  With these procedures, access to the relevant anatomical structures is gained endoscopically through the mouth without skin incisions. Primary and revision bariatric procedures are being developed to reduce the risks associated with open and laparoscopic interventions. Examples of endoluminal bariatric procedures studies include gastroplasty using a transoral endoscopically guided stapler and placement of devices such as a duodenal-jejunal sleeve and gastric balloon.

- **Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S) (no specific CPT code)**
  The SADI-S is a type of type of bariatric surgery with a single anastomosis. It has a restrictive component when reducing the greater curvature of the stomach, but specially a malabsorptive component, as the common channel is also reduced. The objective of this surgical technique is to lessen the intestinal loop where nutrients are absorbed.

- **Stomach Intestinal Pylorus-Sparing Surgery (SIPS) (No specific CPT code)**
  SIPS is a type of weight-loss surgery. It was developed in 2013 by two U.S. surgeons. The SIPS is a modified version of the duodenal switch surgery. The SIPS involves the creation of a 300-cm common channel with a single-anastomosis duodenal enterostomy.

- **Long-Limb Gastric Bypass (i.e., >150 cm) (CPT code 43847)**
  Recently, variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum and length of proximal jejunum is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

- **Laparoscopic Malabsorptive Procedure (CPT code 43645)**
  Code 43645 was introduced in 2005 to specifically describe a laparoscopic malabsorptive procedure. However, the code does not specifically describe any specific malabsorptive procedure.

- **Laparoscopic Gastric Plication (no specific CPT code)**
  Laparoscopic gastric plication is a bariatric surgery procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves two main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction, but specifics of the technique are not standardized.

Comparators
Clinical practice guidelines recommend that comprehensive lifestyle intervention (CLI; i.e., interventions that combine behavioral, dietary, and physical activity components together, should always be provided in conjunction with other weight loss interventions). VA guidelines note that although there is insufficient evidence to recommend a specific number of sessions, most CLIs offer at least 12 intervention sessions in the first 12 months of intervention.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

Percent weight lost (e.g., proportions achieving 5%, 10%, and 15% weight loss or mean difference between groups) is commonly used in studies of interventions. Decrease in BMI can be used, especially if change leads to a change in risk category.

Recommended primary outcome measures are summarized in Table 3.

Table 3. Primary Outcome Measures for Bariatric Surgery Procedures

Outcome	Measures	Clinically Important Difference	Duration of Follow Up
Weight loss	% TBWL	• 5% • FDA: varies (2% to 5%) depending on indication sought (weight loss, limited weight loss, or weight management) • Should be appropriate for associated risk • AACE: for tertiary prevention, based on comorbidities	12 months (6 months if indication is short-term weight loss)
	Responder rate	Proportion achieving at least 5% TBWL • Devices guidance - at least 50% of treated participants • Drugs guidance - at least 35% and double the control group	12 months
Adverse events	Incidence, severity	•Intervention-specific	12 months or longer

AACE: American Association of Clinical Endocrinology; FDA: Food and Drug Administration; TBWL: total body weight loss.

Indirect evidence of the effectiveness of weight loss interventions on health outcomes is provided by studies of the strength of the association between weight loss and health outcomes. AACE (2016) guidelines include a table of weight loss targets for clinical outcomes.[1,]

Direct evidence would come from studies of the effect of the intervention on health outcomes, preferably from randomized controlled trials.

The following secondary outcomes are of interest:

- Percent excess weight loss;
- Change in weight;
- Change in BMI (especially if decrease results in a change to a different risk group);
- Change in waist circumference;
- Patient-reported outcomes and patient preference information;
- Changes in weight-related comorbidities;

The existing literature evaluating any bariatric surgery procedure has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Numerous systematic reviews have compared the efficacy of bariatric surgery with conservative therapy or compared different types of bariatric surgery techniques.[3,4,5,6,] Trials included in select systematic reviews can be compared in Appendix Table A1.

Many systematic reviews have reported improvements in specific obesity-related comorbidities following bariatric surgery. These reviews have relied primarily on the results of observational studies and included the outcomes of hypertension, type 2 diabetes (T2D), hyperlipidemia, cardiovascular events, quality of life, cancer, knee pain, and liver disease.[7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,]

Nonrandomized Studies

Swedish Obese Subjects Trial
The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial was started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34kg/m^2 at 480 primary health care centers in Sweden. From this registry,

patients who met eligibility criteria were recruited and offered bariatric surgery. Thus, SOS patients were self-selected into treatment, and there were baseline differences between groups, primarily reflecting weight that is more excess and a higher incidence of co-morbidities in the surgery group. Participants with hypertension, diabetes, or lipid imbalances were eligible for inclusion, as well as those who had experienced a myocardial infarction or stroke more than six months prior to study inclusion. A total of 2,010 people chose surgery and 2,037 individuals who chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each individual surgeon chose the surgical procedure offered. Most of the procedures were vertical-banded gastroplasty (VBG) (over 70%), with gastric bypass (6%) and gastric banding (23%) procedures performed as well. Usual care in the SOS trial was the local practice of the primary care center and usually did not include pharmacologic treatment. The patients are followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

Many publications from this trial have reported on methods, weight loss, and clinical outcomes.[28,29,30,31,32] The following general conclusions can be drawn from the SOS study:

- Weight loss is greater with bariatric surgery compared to conservative treatment. At 10 years of follow-up, weight loss in the surgery group was 16% of total body weight, compared to a weight gain of 1.6% in the conservative treatment group.
- There is definite improvement in glucose control for diabetics and a reduced incidence of new cases of diabetes.
- The effect on other cardiovascular risk factors, e.g. hypertension and lipidemia is also positive, but less marked than that seen for diabetes
- Mortality is reduced by 29% after a mean follow-up of 10.9 years
- Quality of life shows improvement in the 2-10 year follow-up period, with the degree of improvement in quality of life correlated with the amount of weight loss.
- Bariatric surgery may greatly reduce the risk of cancer among patients with obesity and diabetes. Moreover, diabetes remission at the 10-year follow-up was associated with reduced cancer incidence (adjusted hazard ratio 0.40 [95% CI 0.22 - 0.74], p =.003).

Longitudinal Assessment of Bariatric Surgery Consortium

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium study is a large prospective, longitudinal, noncomparative study of patients who underwent Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding with follow-up through 3 years post procedure.[33] The study enrolled 2458 subjects, with median BMI 45.9 (interquartile range [IQR], 41.7-51.5). At baseline, 774 (33%) had diabetes, 1252 (63%) dyslipidemia, and 1601 (68%) hypertension. For their first bariatric surgical procedure, 1738 participants underwent Roux-en-Y gastric bypass, 610 laparoscopic adjustable gastric banding, and 110 other procedures. At 3-year follow-up, for 1533 Roux-en-Y patients with available data, percentage of baseline weight lost was 31.5% (IQR, 24.6%-38.4%). For the 439 adjustable gastric banding patients with available data at 3 years, percentage of baseline weight loss was 15.9% (IQR, 7.9%-23.0%). At 3 years post-surgery, 67.5% and 28.5% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the Roux-en-Y gastric bypass patients and 17.5% (95% CI, 13.8% to 21.9%) of laparoscopic adjustable gastric banding patients.

National Patient-Centered Clinical Research Network - Bariatric Study

The National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study is a large retrospective, comparative study of 65,093 patients aged 20-79 years who underwent Roux-en-Y gastric bypass (RYGB) (n= 32,208), laparoscopic adjustable gastric banding (LAGB) (n=29,693), or sleeve gastrectomy (SG) (n=3192) with follow-up through five years postprocedure.[34] At baseline, patients across all three study groups suffered from several comorbid conditions, including hypertension (60%), dyslipidemia (49%), sleep apnea (49%), GERD (41%), diabetes (37%), and depression (31%). Mean estimated percent total weight loss (TWL) was calculated at 1, 3, and 5 years in addition to 30-day rates of major adverse events. Study results are summarized in Table 4. This study demonstrates that RYGB is associated with a greater weight loss than SG (p<.001) and that LAGB is associated with the lowest amount of weight loss as observed in a large and diverse patient cohort.

Table 4. National Patient-Centered Clinical Research Network - Bariatric Study Results

	Mean TWL, % (95% CI)			MAE, % (95% CI)
Group (N[a])	**1 Year**	**3 Years**	**5 Years**	**30 Days**
RYGB (19,029; 9225; 3676)	-31.2 (-31.3 to -31.1)	-29.0 (-29.2 to -28.8)	-25.5 (-25.9 to -25.1)	5.0 (NR)
LAGB (1681; 943; 337)	-13.7 (-14.0 to -13.3)	-12.7 (-13.5 to -12.0)	-11.7 (-13.1 to -10.2)	2.9 (NR)
SG (14,929; 5304; 1088)	-25.2 (-25.4 to -25.1)	-21.0 (-21.3 to -20.7)	-18.8 (-19.6 to -18.0)	2.6 (NR)

CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; MAE: major adverse event; NR: not reported; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; TWL: total weight loss.
[a] Number of patients evaluated at 1, 3, and 5 years, respectively.

Evidence for Specific Types of Bariatric Surgery Procedures

Arterburn et al (2021) published a retrospective, matched cohort study to investigate weight loss among patients with severe obesity undergoing RYGB, SG, or nonsurgical treatment.[35] Among 17,258 RYGB, 13,900 SG, and 87,965 nonsurgical patients, the 5-year follow-up rate was 72.0%, 70.9%, and 64.5%, respectively. At 1, 5, and 10 years, RYGB patients had a %TWL of -28.35% (95% CI, -28.53 to -28.18), -21.74% (95% CI, -22.02 to -21.45), and -20.18% (95% CI, -21.00 to -19.34), respectively; at the same time points, nonsurgical patients had a %TWL of -0.22% (95% CI, -0.35 to -0.09), -2.24% (95% CI, -2.46 to -2.02), and -4.78% (95% CI, -5.51 to -4.04), respectively. At 1 and 5 years, SG patients had a %TWL of -22.98% (95% CI, -23.19 to -22.76) and -15.99% (95% CI, -16.58 to -15.40), respectively.

Wadden et al. (2019) reported on end-of-trial results from the Look AHEAD trial, which evaluated outcomes in patients with T2D and obesity who had self-selected to receive bariatric surgery after failing an assigned intensive lifestyle intervention (ILI) or a diabetes support and education (DSE) control therapy.[36] Patients who received bariatric surgery were significantly more likely to be female (p<.001), younger (p<.001), and have higher BMI at randomization (p<.001). Patients underwent 127 RYGB, 58 LAGB, and 11 SG procedures, respectively. End-of-trial assessments were completed at 4.3 years post-surgery compared to 9.6 years post randomization for the DSE and ILI participants. Patients undergoing RYGB, LAGB, or SG surgical procedures lost a mean of 22.4% ± 1.0%, 13.0% ± 1.5%, and 16.2% ± 3.3% of baseline weight, respectively. Twelve patients (6.1%) receiving bariatric surgery were randomized with a BMI <35 kg/m2. The mean BMI was 37.0 ± 5.1, 37.1 ± 5.3, and 42.1 ± 5.8 for DSE, ILI, and surgery groups, respectively (p<.001). Overall, surgically-treated patients lost a mean of 19.3% of baseline weight, compared with 5.8% and 3.3% for the ILI and DSE

participants. Full diabetes remission was achieved by 7.6% of bariatric surgery participants compared to 1.1% of ILI and 1.1% of DSE participants. Full remission was significantly more common in surgically treated participants in ILI (RR 6.72; 95% CI, 3.35 to 13.48; p<.001) or DSE (RR 7.07; 95% CI, 3.49 to 14.30; p<.001) groups. Significantly greater reductions in waist circumference (p<.001), triglyceride levels (ILI: p=.03; DSE: p=.02), and HbA1c levels (p<.001) were observed in surgically-treated patients compared to ILI or DSE groups. The study was limited by heterogeneity in baseline characteristics and choice of surgical procedure. Results were not stratified by surgery type or BMI range.

Laparoscopic Adjustable Gastric Banding

Systematic Reviews

A 2006 TEC Assessment updated the evidence on LAGB, and compared outcomes to those of gastric bypass.[37] This Assessment concluded that for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either open gastric bypass (GBY) or laparoscopic gastric bypass (LAGY) as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (such as extent of weight loss and frequency and timing of potential complications) of the two procedures to allow the optimal choice to be made based on preferences and shared decision making.

Weight loss outcomes from the studies reviewed in the Assessment confirm the conclusions of previous TEC Assessments that weight loss at 1 year is less for LAGB compared with GBY. The percentage of excess weight lost (EWL) at 1 year is in the range of approximately 40%, compared to 60% or higher for GBY. At time points longer than 1 year, some of the comparative studies report that the difference in weight loss between LAGB and GBY lessens, but others do not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up do not support the hypothesis that the difference in weight loss between the procedures begins to lessen after 1 to 2 years of follow-up. It appears more likely from the current data that attrition bias may account for the diminution of the difference in weight loss over time, particularly when patients who have their band removed or deflated are excluded from analysis.

These studies also confirm that short-term (perioperative) complications are very low with LAGB and lower than with either open or laparoscopic GBY. Death is extremely rare, and serious perioperative complications probably occur at rates of less than 1%. The reported rates of long-term AEs vary considerably. In the comparative trials, re-operations are reported in approximately 25% of patients, while in the single-arm studies, the composite rate for re-operations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable; for example, the range of rates for band slippage is 1–36%, and the range for port access problems is 2–20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. It is not possible to determine the precise rates of long-term complications from these data, but it is likely that complications are under-reported in many studies due to incomplete follow-up and a lack of systematic surveillance. A recent publication by Ibrahim et al (2017) reviewed 25,042 Medicare beneficiaries who underwent a laparoscopic gastric band surgery; 18.5% (n=4636) patients underwent one or more reoperation(s). Reoperation was prompted by the need for band removal (41.8%), band and port replacement (28.6%), and other requirements.[38] The rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit/risk ratio for LAGB.

In comparing LAGB with GBY, there is a tradeoff in terms of risks and benefits. LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay, and earlier return to usual activities. However, the benefits, as defined by the amount of weight loss, will also be less for LAGB. The patterns of long-term complications also differ between the two procedures. For LAGB, longer-term adverse events related to the presence of a foreign body in the abdomen will occur and will result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.

A systematic review by Chakravarty et al. (2012)[39] comparing LAGB with other bariatric surgery procedures drew conclusions similar to the TEC Assessment. Reviewers included 5 RCTs. The RCTs found that patients using LAGB lost weight, but less weight than with other procedures (e.g., gastric bypass or sleeve gastrectromy [SG]). However, the short-term complication rate was lower with LAGB and no difference was found in quality of life after LAGB versus other procedures.

Prospective Studies

Dixon et al (2018) published a prospective, industry-sponsored study of morbidly obese patients who underwent implantation of the adjustable gastric banding system (LAP-BAND).[40] Between 2009 and 2013, 652 patients with a mean BMI of 45.4 kg/m^2 were treated at 17 participating centers in the US and Canada. At 5 years, the explant rate was 8.74% (95% CI: 6.6–10.9%). Excluding explants, 100 (15.3%) reoperations were necessary during the follow-up period. A mean weight loss of 18.7% was achieved by 2 years and maintained through 5-year follow-up. The study was limited by the lack of control group.

SLEEVE GASTRECTOMY

Systematic Reviews

Sleeve Gastrectomy may be performed as a stand-alone procedure or in combination with a malabsorptive procedure, such as the biliopancreatic diversion with duodenal switch. It has also been proposed as the first step in a 2-stage procedure, with gastric bypass or biliopancreatic diversion as the second stage.

Numerous recent systematic reviews have compared SG and RYGB with regard to effects on weight, comorbidities, andcomplications.[41-46]

Lee et al (2021) performed a meta-analysis evaluating long-term (5 years) outcomes of laparoscopic RYGB versus SG.[47] A total of 33 studies (N=2475) were included. Results demonstrated that RYGB resulted in a significantly greater decrease of BMI compared to SG at 1 and 3 years post-surgery; results at 5 years did not reach statistical significance. A similar trend was seen for the resolution of dyslipidemia. Furthermore, neither RYGB nor SG was superior for the remission of T2D and hypertension at 5 years. Recent meta-analyses have provided further insights into the long-term remission rates of diabetes and hypertension between these bariatric procedures. A meta-analysis conducted by Elsaigh et al (2024), encompassing 23 RCTs (N=4148), revealed that RYGB significantly improved diabetes remission and resulted in greater total body weight loss compared to SG at up to 10 years of follow-up. However, heterogeneity was observed under sub-group analysis at this study period ($p=.001$, $I^2=75\%$).[48] In another recent meta-analysis of 11 RCTs (N=2323), Zevallos et al. (2024) examined the remission of hypertension after SG versus RYGB. Their findings showed

a notable difference in hypertension remission rates at ≥ 5 years, favoring RYGB (relative risk: 1.39, 95% CI 1.06-1.82, p=.02).[49]

Gu et al (2020) completed a meta-analysis of the medium- and long-term effects of laparoscopic SG and RYGB (Table4).[41] The evaluation included 9038 patients from 28 studies. Overall, 5 year follow-up results revealed that laparoscopic RYGB was associated with an improvement in percentage of EWL and remission of T2D, hypertension, and dyslipidemia as compared to laparoscopic SG. Han et al. (2020) also published a systematic review and meta-analysis involving 18studies (N=2917) that compared weight loss and comorbidity resolution between laparoscopic SG and RYGB (Table 4).[42] Results from this analysis revealed no significant difference in EWL or T2D resolution between the 2 procedures. Laparoscopic RYGB was found to be superior to SG with regard to dyslipidemia, hypertension, and GERD management; however, patients who underwent laparoscopic SG experienced fewer postoperative complications and reoperation rates. Similarly, in an updated meta-analysis by Memon et al (2024) of 5 RCTs (N=1093) of postoperative GERD data comparing laparoscopic SG and laparoscopic RYGB in adults, SG was associated with increased adverse GERD outcomes compared to RYGB at 5 years.[50] Overall, SG was associated with significantly more interventions (both medical and surgical) for either worsening GERD and/or development of de novo GERD compared to RYGB (odds ratio 5.98, 95% CI 3.48-10.29; p≤.01; I^2 =0%) Moderate level of certainty).

Sharples et al (2020) performed a systematic review and meta-analysis evaluating long-term (5 years) outcomes of RYGB and SG (Table 4).[43] Overall, both RYGB and SG resulted in sustained weight loss and comorbidity control with RYGB associated with a greater percent EWL, improved dyslipidemia outcomes.

Shenoy et al (2020) published a systematic review and meta-analysis of 9 studies that compared laparoscopic SG and RYGB in 2240 elderly (>55 years) patients.[44] Results revealed no significant differences between the 2 bariatric procedures with regard to the rate of early complications (3.6% LSG versus 5.8% LRYGB; p=.15) and mortality (0.1% versus 0.8%; p=.27). Additionally, there was no difference in EWL between the procedures at 1 year; however, the authors recommended SG for high-risk elderly patients due to the reduced mortality and complication rates with this procedure. Another systematic review and meta-analysis by Xu et al. (2020) involving 19 studies also concluded that SG was the preferable option for elder obese patients 60 years and older as it was found to be non-inferior to RYGB with regard to efficacy, but overall had an improved safety profile.[51]

Osland et al (2017) published a systematic review and meta-analysis of RCTs comparing laparoscopic vertical SG with RYGB.[52] The literature search, conducted from 2000 to November 2015, identified 9 RCTs for inclusion (total N=865 patients). Four trials were included in meta-analyses comparing percent EWL between the 2 groups. Results at both 6- and 12-month follow-ups showed that the procedures are comparable. Osland et al (2020) recently published a continuation of their work that focused exclusively on long-term (5 year) weight outcomes of laparoscopic vertical SG versus RYGB.[53] This systematic review and meta-analysis included 5 studies (SG=520; RYGB=508) and results revealed that a statistically significant BMI loss was seen with both SG: -11.37 kg/m2 (range: -6.3 to -15.7 kg/m2) and RYGB: -12.6 kg/m2 (range: -9.5 to -15.4 kg/m2) at 5 years. However, differences in reporting parameters limit the ability to reliably compare outcomes using statistical methods and the results may have been impacted by large dropout rates and per protocol analyses of the 2 largest included studies.

A systematic review by Juodeikis and Brimas (2017) summarized evidence on long-term results after SG.[54] Reviewers included 1 RCT and 19 retrospective studies, with a total of 2713 patients who received SG. Mean preoperative BMI was 46.9 kg/m^2. Mean duration of follow-up ranged from 5 to 11 years and mean proportion of patients followed for 5 years was 68.5%. Seventeen studies (N=1501 patients) reported 5-year follow-up data. At 5 years, resolution of T2D arterial hypertension, dyslipidemia, OSA, gastroesophageal reflux disease (GERD), and degenerative joint diseases also improved in most patients. Two studies reported weight loss after 7 and 8 years; percent EWL rates were 56.6% and 54.8%, respectively.

In a meta-analysis of 21 randomized and nonrandomized studies (total N=18,766 patients) comparing SG with LRYGB for morbid obesity, Zhang et al. (2015) reported no significant difference in percent EWL from 0.5 to 1.5 year follow-ups.[55] However, after 1.5 years, Roux-en-Y bypass was associated with higher percent EWL (2-year MD=5.77; 95% CI, 4.29 to 7.25; p<.05). Adverse events were more frequent following Roux-en-Y bypass (OR for major complication, 1.29; 95% CI, 1.22 to 3.22; p<.01).

Trastulli et al (2013) conducted a systematic review of randomized trials that compared SG with other bariatric procedures.[56] Summary statistics were provided; meta-analyses were not conducted. The authors reported mean complication rates with SG of 12.1% (range, 10%-13.2%) compared with 20.9% with LAGB (range, 10%-26.4%). Percent EWL ranged from 49% to 81% with SG compared with 62.1% to 94.4% with LAGB.

Brethauer et al (2009) reviewed 36 studies (n=2570) for a systematic review of SG as a staged and primary procedure, the largest number coming from European centers.[57] Thirteen studies (n=821) reported on high-risk patients having a staged approach and 24 studies (n=1,749) on SG as primary procedure. Mean percentage of excess weight loss (% EWL) was reported in 24 studies (n=1,662) and was 55.4% overall (range, 33–85%). Mean postoperative BMI was reported in 26 studies (n=1940) and decreased from a baseline mean of 51.2 to 37.1. Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost, and all had significant reductions from baseline. The rate of major postoperative complications ranged from 0% to 23.8% for all studies and 0% to 15.3% in studies with greater than 100 patients. Leaks (2.2%), bleeding episodes requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical intervention (0.6%) were reported in the 33 studies reporting detailed complication data (n=2,570). All extracted studies reported mortality data with 5 deaths within 30 days of surgery (overall mortality rate 0.19%, 2 in the high-risk/staged group and 3 in the primary procedure group).

Table 5. Systematic Review Characteristics for Sleeve Gastrectomy

Study	Dates	Studies	Participants	Design	Duration
Lee et al (2021) [47]	Through Jan 2019	33	SG=1252; RYGB=1223	RCTs	1 to 5 y
Gu et al. (2020) [41]	Through Jan 2019	28	SG=4597; RYGB=4441	7 RCTs; 6 prospective; 15 retrospective	3 to 7 y

Han et al. (2020)[42]	Through Jan 2020	18	2917	9 RCTs; 9 nonrandomized studies of interventions	1 to 82.2 mo
Sharples et al. (2020)[43]	Through Dec 2018	5	729	RCTs	5 y
Shenoy et al. (2020)[44]	1991 to 2019	9	SG=683; RYGB=1557	RCTs; observational studies	Minimum follow-up: 1 y
Osland et al. (2017)[52]	2000 to Nov 2017	9	SG=437; RYGB=428	RCTs	3 mo to 5 y
Juodeikis et al. (2017)[54]	Through May 2016	20	1626	1 RCT; 19 retrospective	5 to 11 y
Zhang et al. (2015)5[5]	Through Oct 2013	21	18,766	8 RCTs; 13 nonrandomized comparative	1 to 5 y
Trastulli et al. (2013)[56]	Through Nov 2012	15	1191	RCTs	6 mo to 3 y
Brethauer et al. (2009)[57]	1996 to 2009	36	2570	2 RCTs; 1 cohort; 33 case series	3 mo to 5 y

RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Table 6. Systematic Review Results for Sleeve Gastrectomy

Study	Percent EWL (95% CI)	Comorbidities (95% CI)
Lee et al (2021)[47]	Mean difference SG vs RYGB: 1 y (16 trials): -1.25 kg/m2 (-2.01 to -0.49) 3 y (5 trials): -1.71 kg/m2 (-2.68 to -0.74) 5 y (4 trials): -1.46 kg/m2 (-3.15 to 0.23)	Remission, SG vs RYGB: T2D (1 y): RR, 0.86 (0.71 to 1.04) T2D (3 y): RR, 0.88 (0.72 to 1.07) T2D (5 y): RR, 0.79 (0.57 to 1.10) Hypertension (5 y): RR, 0.86 (0.68 to 1.10) Dyslipidemia (5 y): RR, 0.68 (0.46 to 1.23)
Gu et al (2020)[41]	Weighted mean difference, RYGB and SG: 3 y (13 trials): -4.37 (-8.10 to -0.64) 5 y (9 trials): -2.20 (-3.83 to -0.57)	Remission, RYGB and SG: Type 2 diabetes (3 y): OR, 0.68 (0.48 to 0.95) Type 2 diabetes (5 y): OR, 0.63 (0.41 to 0.96) Hypertension (5 y): OR, 0.51 (0.38 to 0.68) Dyslipidemia (5 y): OR, 0.3 (0.19 to 0.48)
Han et al (2020)[42]	Mean difference, RYGB and SG: RCTs: -0.16 (-0.52 to 0.19)	Resolution, RYGB and SG: Type 2 diabetes: RR, 1.07 (0.89 to 1.28) Dyslipidemia: RR, 1.36 (1.17 to 1.59) Hypertension: RR, 1.23 (1.04 to 1.45) GERD symptoms: RR, 0.16 (0.06 to 0.44)
Sharples et al (2020)[43]	5 y: RYGB: 65.7% SG: 57.3%	RYGB vs. SG at 5 y: Type 2 diabetes resolution: 37.4% vs. 27.5% Diabetes improvement: 77.5% vs. 74% Hypertension resolution: 60.1% vs. 48.4% Hypertension improvement: 86.4% vs. 76.6% Dyslipidemia resolution: 68.6% vs. 55.2% GERD remission: 60.4% vs. 25%

Shenoy et al (2020)[44]	Mean difference, RYGB and SG: -7.79 (-23.96 to 8.38)	Resolution, RYGB and SG: Type 2 diabetes (5 studies): OR, 1.02 (0.63 to 1.66) Hypertension (4 studies): OR, 0.57 (0.35 to 0.93) Obstructive sleep apnea (2 studies): OR, 1.14 (0.55 to 2.34)
Osland et al (2017)[52]	Mean difference, SG and RYGB: 6 mo (3 trials): 0.5 (-5.0 to 6.0) 12 mo (2 trials): 7.6 (-0.1 to 15.3)	NR
Juodeikis et al (2017)[54]	Mean rates for SG: 5 y (17 trials): 58.4% 7 y (2 trials): 56.6% 11 y (1 trial): 62.5%	Remission/improvement: Type 2 diabetes: 77.8% Hypertension: 68.0% Dyslipidemia: 65.9% Sleep apnea: 75.8%
Zhang et al (2015)[55]	Mean difference, RYGB and SG: 6 mo (9 studies): 0.2 (-2.5 to 2.9) 12 mo (15 studies): 2.9 (-0.2 to 6.0) 4 y (3 studies): 2.7 (0.2 to 5.2)	Mean difference resolution, RYGB and SG: Type 2 diabetes (10 studies): 3.3 (2.0 to 5.5) Hypertension (10 studies): 1.3 (0.7 to 2.4) Dyslipidemia (5 studies): 1.1 (0.3 to 1.3) Sleep apnea (7 studies): 1.5 (0.8 to 2.6)
Trastulli et al (2013)[56]	Mean by procedure: SG: 49% to 81% LGB: 62% to 94% LAGB: 29% to 48%	Type 2 diabetes: SG, 67% to 100% LGB, 80% to 100%
Brethauer et al (2009)[57]	Mean rate overall for SG: 55% (range, 33% to 85%)	Remission/improvement: Type 2 diabetes: >70% Significant reductions also seen in hypertension, hyperlipidemia, and sleep apnea

BMI: body mass index; CI: confidence interval; EWL: excess body weight loss; GERD: gastroesophageal reflux disease; LAGB: laparoscopic adjustable gastric banding; LGB: laparoscopic gastric bypass; NR: not reported; OR: odds ratio; RCT: randomized controlled trial; RR: relative risk; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Randomized Controlled Trials

Hofsø et al (2019) published the results of a single-center, triple-blind RCT comparing the efficacy of Roux-en-Y gastric bypass (RYGB) (n=54) vs. sleeve gastrectomy (SG) (n=55) on diabetes remission and ß-cell function in patients with obesity and T2D.[58] Inclusion criteria included previously verified BMI ≥35 kg/m^2 and current BMI ≥33.0 kg/m^2, hemoglobin A1c (HbA1c) ≥6.5% or use of antidiabetic medications with HbA1c ≥6.1%, and age ≥18 years. One-year follow-up was completed by 107 (98%) of 109 patients, with 1 patient in each group withdrawing after surgery. In the intention-to-treat population, diabetes remission rates were superior in the gastric bypass group than in the sleeve gastrectomy group (risk difference 27%; 95% CI, 10 to 44; relative risk [RR] 1.57, 95% CI, 1.14 to 2.16; p=.0054). Results were similar in the per-protocol population (risk difference 27%; 95% CI, 10 to 45; RR 1.57; 95% CI, 1.14 to 2.15; p=.0036). The two procedures had a similar beneficial effect on ß-cell function.

Peterli et al (2018) published a randomized study of adults with morbid obesity treated with either laparoscopic sleeve gastrectomy (SG) or Roux-en-Y gastric bypass (RYGB).[59] Two hundred five patients (mean age, 45.5 years; mean BMI, 43.9; 72% women) treated at 4 Swiss bariatric centers were randomly assigned to receive SG (n=101) or RYGB (n=104) with 5-year follow-up. Excess BMI loss was 61.6% for SG and 68.3% for RYGB (95% CI: -14.30 to -0.06; p=.22). Gastric reflux remission was seen in 25.0% of SG and 60.4% of RYGB patients. Reoperations or interventions were necessary for 16/101 (15.8%) in the SG group and 23/104 (22.1%) of the RYGB group. The study was limited by the lack of analysis of diabetes remission information, and the results may not be generalizable.

Salminen et al (2018) published a randomized trial (SLEEVEPASS) comparing 5-year outcomes of morbidly obese patients (n=240; mean age, 48 years; mean baseline BMI, 45.9; 69.6% women) who underwent either laparoscopic sleeve gastrectomy (SG; n=121) or Roux-en-Y gastric bypass (RYGB; n=119).[60] Five-year estimated mean percentage excess weight loss was 49% (95% CI: 45–52%) for sleeve gastrectomy and 57% (95% CI: 53–61%) for gastric bypass. For SG and RYGB, respectively, rates of remission of type 2 diabetes were 37% (n=15/41) and 45% (n=18/40; p>.99). Medication for hypertension was discontinued in 20/68 (29%) SG patients and 37/73 (51%) RYGB patients (p=.02). Overall, 5-yr morbidity rate was 19% for SG and 26% for RYGB (p=.19), and there was no significant difference in QOL between groups (p=0.85). The study was limited by the following: (1) only a small number (n=430) of bariatric procedures were performed in Finland at trial initiation in 2008, meaning a learning curve could account for some earlier technical complications, (2) the study had a higher reoperation rate for sleeve gastrectomy than other trials reported, (3) approximately 20% of patients were lost to follow-up, and (4) there was a lack of reliable information for diabetes duration at baseline.

Wolnerhanssen et al (2021) pooled 5-year outcomes data from the 2018 studies by Peterli et al and Salminen et al. [61] Five-year follow-up was available for 199 of 228 patients after SG and 199 of 229 after RYGB. Patients who underwent SG had an estimated 7% greater excess BMI loss versus RYGB (p<.001). While remission rates for hypertension were better after RYGB versus SG (60.3% vs 44.9%; p<.049), between-group differences in rates of remission of T2D, OSA, or quality of life scores did not reach statistical significance. The rate of complications was higher after RYGB versus SG (37.2% vs 22.5%; p=.001), but there was no difference in mean Comprehensive Complication Index value (30.6 vs 31.0 points; p=.859).

An RCT comparing short-term outcomes of laparoscopic sleeve gastrectomy with gastric bypass was published in 2012.[62] The authors compared 30-day outcomes of 117 patients randomized to gastric bypass with 121 patients randomized to sleeve gastrectomy. There were no deaths in either group. The rate of major complications was 9.4% in the gastric bypass group compared to 5.8% in the sleeve gastrectomy group (p=.29). Minor complications were more common in the gastric bypass group compared to sleeve gastrectomy (17.1% versus 7.4%, p=.02), as was combined major and minor complications (26.5% versus 13.2%, p=.01).

Karamanakos et al (2008) carried out a double-blind RCT to compare outcomes of laparoscopic RYGB and laparoscopic sleeve gastrectomy (LSG) on body weight, appetite, fasting, and postprandial ghrelin and peptide-YY (PYY) levels at 1, 3, 6, and 12 months after surgery.[63] Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI were marked and comparable in each group. EWL was greater after LSG than laparoscopic RYGB at 6 months (55.5% vs. 50.2%; p=.04) and 12 months (69.7% vs. 60.5%; p=.05), all respectively. Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but decreased more after LSG.

Himpens et al (2006) reported on a randomized trial comparing LAGB and laparoscopic isolated SG in 80 patients and reported 3 year follow-up.[64] Median baseline BMI was 37 kg/m^2 (range, 30-47) in the LAGB groups and 39 kg/m^2 (range, 30-53) in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, GERD, complications, and reoperations were recorded at 1- and 3-year follow-ups. Median decrease in BMI in the gastric bypass group was 15.5 kg/m^2 (range, 5-39) after 1 year and 18 kg/m^2 (range, 0-39) at 3 years after LAGB. One year after SG, decrease in BMI was 25 kg/m^2 (range, 0-45) and 27.5 kg/m^2 (range, 0-48) after

3 years. Median EWL in the LAGB group was 41.4% after 1 year and 48% at 3 years. Median EWL after SG was 58% and 66% at 1 and 3 years, respectively. More patients having SG than LAGB reported loss of craving for sweets, but the difference was not statistically significant; GERD appeared de novo in more SG than LAGB patients at 1 year, and the relation reversed at 3 years; between-group differences were not statistically significant at either time point. Two SG patients required reoperation for complications. Seven late complications required reoperation after LAGB, including pouch dilations treated by band removal (n=2) or conversion to RYGB (n=1), 1 gastric erosion treated by conversion to RYGB, and 3 system disconnections that required reconnection. Four patients had reoperations for lack of efficacy (2 LAGB patients underwent conversion to RYGB, 2 SG patients underwent conversion to duodenal switch). The authors noted that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group.

BILIOPANCREATIC DIVERSION WITH DUODENAL SWITCH (BPD WITH DS)

Systematic Reviews

In an evidence-based review of literature, Farrell et al (2009) summarized data on BPD with or without DS, RYGB (proximal), and adjustable gastric band (AGB) and report that at the mean of 1-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (4 studies, aggregate n=896 patients), 67% for RYGB (7 studies, n=1,627), and 42% for AGB (11 studies, n=4,456 patients).[65] At mean follow-up of 5 years, EWL for BPD with or without DS was 73% (3 studies, aggregate n=174 patients), 58% for RYGB (3 studies, n=176 patients), and 55% for AGB (5 studies, n=640 patients). The authors note that “given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for one procedure over another.”

Esparaham et al. (2024) conducted a meta-analysis of 12 studies (N=2678) with follow-up periods ranging from 1 to 15 years, to evaluate the comparative outcomes of DS and RYGB in individuals with a BMI of ≥50 kg/m^2.[66.] The findings indicated that DS resulted in significantly more substantial reductions in BMI and overall weight loss within this cohort when compared to RYGB. However, DS was linked to a higher incidence of major malnutrition (8.3% vs. 1.2% in RYGB; OR: 5.53, 95% CI: 1.35-22.44, p=.02), as well as an increased risk of developing gallbladder disease requiring cholecystectomy (24.6% vs. 4.5% post-RYGB; OR: 6.36, 95% CI: 1.70–23.82, p=.01).

Randomized Controlled Trials

Salte et al (2024) conducted an open-label RCT (N=60) at two academic bariatric centers in Sweden and Norway.[67.] The study aimed to compare long-term outcomes, specifically weight loss, health parameters, and quality of life following either DS or RYGB surgeries in patients with a body mass index (BMI) of 50 to 60kg/m^2. Forty-eight (of 60) patients (80%) were assessed after a median of 12 (range, 9-13) years. At follow-up, the mean BMI reductions were 20.3 (95% CI, 17.6-23.0) for DS and 11.0 (95% CI, 8.3-13.7) for RYGB, with a mean between-group difference of 9.3 (95% CI, 5.4-13.1; p<.001). Total weight loss was 33.9% (95% CI, 27.8%-40.0%) for DS and 20.0% (95% CI, 15.3%-24.7%) for RYGB (p=.001).

Mean serum lipid levels, except high-density lipoprotein cholesterol and HbA1c, improved more in the DS group during follow-up. Bone mass was reduced for both groups from 5 to 10 years, with lower bone mass after DS at 10 years. Quality-of-life scores (Obesity-Related Problem Scale and the 36-Item Short Form Health Survey) were comparable across groups at 10 years. The total number of adverse events was higher after DS (135 vs 97 for RYGB; p=.02). More patients in the DS group developed vitamin deficiencies (21 vs 11 for RYGB; p=.008) and 4 (of 29) patients in the DS group (14%) developed severe protein caloric malnutrition, of whom 3 (10%) underwent revisional surgery. These findings indicate that while DS facilitates more significant BMI reduction over time and offers some cardiometabolic advantages, it also incurs nutritional deficiencies and adverse effects. The small sample size is a notable limitation, suggesting that the evaluation of several outcomes should be approached with caution.

Bariatric Surgery for Adults with Class 1 Obesity and Type 2 Diabetes

Clinical Context and Therapy Purpose

The purpose of gastric bypass, SG, BPD, and adjustable gastric banding is to provide treatment options that are alternatives to or improvements on existing therapies, such as standard medical care, in patients who have Class 1 obesity and T2D.

Resolution (cure) or improvement of T2D after bariatric surgery and observations that glycemic control may improve immediately after surgery before a significant amount of weight is lost have promoted interest in a surgical approach to the treatment of T2D. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides (e.g., glucagon-like peptide-1, glucose-dependent insulinotropic peptide, and peptide YY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. Glucagon-like peptide-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. Glucose-dependent insulinotropic peptide acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as glucagon-like peptide-1, although it is less potent. Peptide YY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.
The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who have Class 1 obesity and T2D.

Interventions

The therapy being considered is gastric bypass, SG, BPD, and adjustable gastric banding. Current indications for bariatric surgery view poorly or uncontrolled T2D as a comorbidity whose presence supports the need for surgery in individuals with a BMI of less than 35 kg/m^2.

Comparators

Comparators of interest include standard medical care. Treatment for individuals with T2D includes blood glucose regulation and insulin therapy.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating gastric bypass, SG, BPD, and adjustable gastric banding as a treatment for T2D has varying lengths of follow-up, ranging from 1 to 5 years.

While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

This section focuses on RCTs and systematic reviews of RCTs comparing bariatric surgery with medical therapy.

Review of Evidence

Systematic Reviews

Multiple systematic reviews have evaluated bariatric surgery compared to nonsurgical interventions for individuals with T2DM.[68,69,70,71,72,73,74,]

The most recent systematic review has been conducted by Thomas et al (2023) to assess the clinical efficacy and safety of bariatric surgery compared with medical management in adults with class I obesity and difficult-to-manage T2DM, with or without other comorbidities.[68] The analysis included 4 RCTs and 8 comparative observational studies, alongside a AHRQ systematic review published in 2023). Of the twelve studies, ten were conducted internationally, while the remaining two, consisting of one RCT and one retrospective cohort study, were conducted in the United States. Of the included studies, 7 assessed RYGB alone (3 RCTs and 4 observational studies), and 3 studies assessed bariatric surgery as a combination of RYGB and sleeve gastrectomy (1 RCT, which also had a small proportion of gastric banding, and 2 observational studies), and 2 studies assessed biliopancreatic diversion with duodenal switch. There were no studies assessing single anastomosis duodeno-ileal bypass with sleeve gastrectomy in this study population.

Complete diabetes remission was reported in 4 RCTs and 6 observational studies. In general, 3 (of 4) RCTs found significantly higher remission rates in those receiving bariatric surgery compared with those receiving various forms of medical management. Remission rates in the studies ranged from 65% at the 6-month follow-up to 38%-42% at the 5-year follow-up for bariatric surgery, compared with 0% at both timepoints in the comparator. The remaining RCT reported a difference in diabetes remission between RYGB and medical management that was not statistically significant (44.5% vs. 24.4%, p =.05). In the observational studies, complete diabetes remission rates ranged from 25% to 100% for bariatric surgery compared with 0% to 3.5% for medical management. Change in BMI from baseline was reported in 4 RCTs and 8 observational studies. Overall, in the RCTs, there were reductions in BMI ranging from −5 to −9 kg/m2 for bariatric surgery and from −0.8 to −3.4 kg/m2 for medical management. Notably, reductions in BMI appeared to remain after up to 5 years of follow-up. Similarly, in the observational studies, reductions in BMI ranged from −1 to −8.8 kg/m2 for bariatric surgery and from 2.4 to −1.8 kg/m2 for medical management at 1 month to 10 years of follow-up.
The quality of evidence (GRADE) from RCTs and observational studies was assessed as Low to Very Low for both complete diabetes remission and BMI changes across multiple follow-up periods. The investigators reported that bariatric surgery may also reduce the use of medications for type 2 diabetes (GRADE: Low) and may improve quality of life (based on one study) compared with medical management (GRADE: Low). A meta-analysis was not performed due to the clinical and methodological heterogeneity in the patient populations, follow-up periods, definitions of medical management (i.e., the comparator used), and outcome definitions (diabetes remission, medication use). The RCTs involved were limited by their small sample sizes (N ≤ 100) and the potential for bias due to unbalanced attrition among treatment groups. Similarly, the observational cohort studies faced limitations from small sample sizes (with 6 out of 8 studies involving fewer than 100 participants) and risk of bias concerns associated with confounding factors and participant selection, which are inherent challenges in this study design.

Wu et al (2016) published a meta-analysis of studies comparing bariatric surgery with nonsurgical interventions for patients who had T2D.[70] Eight RCTs with 619 patients were included. RCTs addressed RYGB (6 studies), LAGB (3 studies), LSG (1 study), and BPD (1 study). Mean BMI across studies was 29 kg/m2 or higher; in 6 of 8 studies, mean BMI was 35 kg/m2 or higher. One study had a 5-year follow-up, and the others had 1 to 3 years of follow-up. The study with a 5-year follow-up, by Mingrone et al (2015), was limited to patients with a BMI of at least 35 kg/m2.[75] All 8 studies reported remission of T2D as an efficacy endpoint. A pooled analysis found a significantly higher rate of T2D remission in the bariatric surgery versus the nonsurgical treatment group (RR, 5.76; 95% CI, 3.15 to 10.55; p<.001). Another diabetes-related outcome (mean reduction in HbA1c levels) was significantly greater after bariatric surgery than nonsurgical treatment (MD, -1.29; 95% CI, -1.70 to -0.87). Also, there was a significantly greater reduction in BMI with bariatric surgery than with nonsurgical treatment (MD, -5.80; 95% CI, -6.95 to -4.64; p<.001). Since the publication of the Wu et al (2016) meta-analysis, 5-year follow-up has been reported for the Schauer et al (2017) RCT, which is shown in Table 18. When the Wu et al (2016) meta-analysis was published, only 3-year findings of the Schauer et al (2017) study were available. The study included patients with T2D who had a BMI of 27 to 43 kg/m2.

Yan et al (2016) published a systematic review of RCTs comparing gastric bypass with medical treatment in obese patients (i.e., BMI ≥30 kg/m2) who had T2D.[69] The primary study outcome was remission of T2D, which was reported in 5 of the 6 studies. A pooled analysis found a significantly higher remission rate after gastric bypass than after medical treatment

(OR, 76.37; 95% CI, 20.70 to 271.73; p<.001). Also, a pooled analysis found a significantly lower final BMI in the gastric bypass group than in the medical treatment group (MD, -6.54 kg/m2; 95% CI, -9.28 to -3.80 kg/m2; p<.001).

Muller-Stich et al (2015) published a systematic review of RCTs and observational studies on bariatric surgery in patients with T2D and a BMI less than 35 kg/m2.[73] Eleven comparative trials of medical therapy versus bariatric surgery were included, with 5 RCTs and 6 nonrandomized comparative studies identified. Follow-up was between 1 and 3 years. The primary outcome reported was remission of diabetes. On combined analysis, bariatric surgery was associated with a higher remission rate than medical therapy (OR, 14.1; 95% CI, 6.7 to 29.9; p<.001). On secondary outcomes, surgery was associated with a greater decrease in BMI (MD, -5.5 kg/m2; 95% CI, -6.7 to -4.3; p<.001), a lower HbA1c level (MD, -1.4%; 95% CI, -1.9 to -0.9; p<.001), lower rates of hypertension (OR, 0.25; 95% CI, 0.12 to 0.50; p<.001), and lower rates of dyslipidemia (OR, 0.21; 95% CI, 0.10 to 0.44; p<.001).

Rao et al (2015) published a meta-analysis of short-term outcomes for patients with T2D and a BMI of 35 kg/m2 or less who underwent RYGB.[74] Nine articles were included (N=343 patients). After 12 months, patients with T2D had a significant decrease in BMI (weighted MD, -7.42; 95% CI, -8.87 to -5.97; p<.001) and improvements in HbA1c levels (weighted MD, -2.76; 95% CI, -3.41 to -2.11; p<.000). Reviewers reported that longer term follow-up would be needed.

Section Summary: Bariatric Surgery in Adults with Class 1 Obesity and Type 2 Diabetes
Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in adults with obesity, including those with a BMI between 30 and 34.9 kg/m2. The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The quality of evidence (GRADE) from RCTs and observational studies was assessed as Low to Very Low for both complete diabetes remission and BMI changes across multiple follow-up periods. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 5 years of follow-up data. Most RCTs in this population have 1 to 5 years of follow-up data.

BARIATRIC SURGERY IN NONDIABETIC PATIENTS WITH A BMI LESS THAN 35 KG/M^2 WHO DO NOT HAVE TYPE 2 DIABETES

Clinical Context and Therapy Purpose
The purpose of any bariatric surgery procedure is to provide a treatment option that is an alternative to or improvement on existing therapies, such as standard medical care, in patients who are not diabetic and do not have class III obesity.

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest are individuals with a BMI less than 35 kg/m2 who do not have type 2 diabetes.

Interventions
The therapy being considered is any bariatric surgery procedure.

Comparators
Comparators of interest include standard medical care for nondiabetic patients.

Outcomes
The general outcomes of interest are overall survival, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating any bariatric surgery procedure has varying lengths of follow up, ranging from 1 to 3 years. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5-10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
A 2012 TEC Assessment evaluated laparoscopic gastric banding in individuals without diabetes who had a BMI less than 35 kg/m^2.[144] This Assessment was prompted by FDA approval of LAP-BAND for this indication in 2011. The TEC Assessment concluded that LAGB did not meet TEC criteria in these patients and made the following summary statements:

- The evidence on LAGB for patients with lower BMIs is limited both in quantity and quality. There is only 1 small RCT, which has methodologic limitations, 1 nonrandomized comparative study based on registry data, and several case series. Using the GRADE evaluation, the quality of evidence on the comorbidity outcomes was judged to be low and the quality of the evidence on the weight loss outcomes was judged to be moderate.
- The evidence was sufficient to determine that weight loss following LAGB is greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities was lacking. The limited evidence was not sufficient to conclude that the amount of weight loss is large enough that improvements in weight-related comorbidities can be assumed.
- There was very little data on quality of life in this population of patients.
- The frequency and impact of long-term complications following LAGB were uncertain, and this uncertainty has been one of the main reasons why it is difficult to determine whether the benefit of LAGB outweighs the risk for this population. While the short-term

safety of LAGB has been well-established, the long-term adverse effects occur at a higher rate and are less well-defined.

Section Summary: Bariatric Surgery in Nondiabetic Patients With a BMI Less Than 35 kg/m^2

There is limited evidence for bariatric surgery in patients who are not diabetic and have a BMI less than 35 kg/m2. A few small RCTs and case series have reported loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population.

Bariatric Procedures Other than Open or Laparoscopic Gastric Bypass using a Roux-en-Y, Laparoscopic Adjustable Gastric Banding, Open or Laparoscopic Sleeve Gastrectomy, or Open or Laparoscopic Biliopancreatic Bypass/Diversion with Duodenal Switch

This section briefly summarizes the key evidence on additional bariatric procedures that are used infrequently.

Biliopancreatic Diversion without Duodenal Switch

A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without the DS and gastric bypass.[37] However, BPD without DS leads to complications, especially long-term nutritional and vitamin deficiencies.[77,78]

Vertical-Banded Gastroplasty

A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG with gastric bypass.[79] The Assessment found that weight loss was significantly greater with open gastric bypass than with VBG. Also, VBG has relatively high rates of complications, revisions, and reoperations.

Two-Stage Bariatric Surgery Procedures

The evidence from an RCT [80] and several case series [81,82,83] does not support a 2-stage bariatric surgery procedure for improving outcomes in patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced by this approach. Most patients who receive SG as the initial procedure lose sufficient weight during the first year so that a second procedure is no longer indicated. Also, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is likely that overall complications are increased by this approach.

Laparoscopic Gastric Plication

There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication with other bariatric surgery procedures. A 2021 systematic review demonstrated that SG is superior to greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months.[84] The difference in the improvement of comorbidities and risk of major complications or mortality did not reach statistical significance between groups. One RCT compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention.[85] Longer-term follow-up and additional comparative studies are needed.

Single Anastomosis Duodeno-ileal Bypass With Sleeve Gastrectomy (SADI-S)

Esparham et al. (2024) conducted a systematic review of 10 studies (N=1707 patients) to examine the mid- and long-term outcomes of single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S).[86] The included studies focused on laparoscopic SADI-S procedures with follow-up periods of ≥ 3 years (ranging from 3 to 10 years). The percentage of excess weight loss (%EWL) ranged from 71% to 89%, with an average of 80% at six and ten years, respectively. The most common late complications observed were malabsorption (6.3%) and GERD (3.6%). Remission rates for hypertension, diabetes, GERD, obstructive sleep apnea, and dyslipidemia varied between 43% and 81%. In conclusion, SADI-S is a safe and effective surgical technique with durable weight loss and a high rate of comorbidity resolution in mid and long term.

In a recent Swedish RCT by Axer et al (2024), the clinical outcomes of SADI-S were compared to those of biliopancreatic diversion with duodenal switch (BPD/DS). Fifty-six patients, with BMI values between 42 and 72 kg/m², were randomly assigned to either the SADI or BPD/DS group.[87] After one year, both procedures demonstrated similar weight loss outcomes (%EWL: 81.8% ± 13.6% vs. 84.2% ± 14.0%; percentage of total weight loss [%TWL]: 40.1% ± 5.9% vs. 41.6% ± 6.4%). Early complications occurred in five patients in the SADI group and in four patients in the BPD/DS group with no mortality. Median length of stay was 2 days for both SADI and BPD/DS. Within 30 days, one SADI patient and three BPD/DS patients required re-admission. Serious late complications necessitating reoperation were observed in three SADI and two BPD/DS patients. This trial suggests that both the SADI and BPD/DS yield comparable weight loss outcomes after 1 year, with a notable risk profile.

Shoar et al. (2018) published a systematic review of 12 studies, comprising 5 cohorts, 4 case series, and 3 case reports, that reviewed the efficacy and safety of SADI-S.[88] The studies included 581 patients who underwent SADI-S. These patients were between 18 and 71 years of age with a BMI between 33 to 71.5 kg/m2. Of the total surgeries, 508 (87.4%) were primary and 73 (12.6%) were revisional. Follow-up was available between 6 and 60 months after the procedure. Results revealed the average percent EWL was 30% at 3 months, 55% at 6 months, 70% at 1 year, and 85% at 2 years. The comorbidity resolution rate was 74.1% for T2D, 96.3% for hypertension, 68.3% for dyslipidemia, 63.3% for OSA, and87.5% for GERD. The most common complication was diarrhea (1.2%) and vitamin A, selenium, and iron deficiency were the most common nutritional deficiencies. There was also the possibility of protein malnutrition in up to 34% of patients when measured. The authors concluded that SADI-S was associated with a promising short-term weight loss outcome and comorbidity resolution rate; however, RCTs are warranted to compare this procedure to more commonly performed bariatric procedures.

Cottam et al (2020) noted that the single-anastomosis duodenal switch (SADS) procedure has been suggested to be an effective bariatric procedure that offers excellent weight loss (WL) and by lengthening the common channel the potential to reduce micro-nutrient deficiencies.[89] These researchers examined the WL, co-morbidity resolution and the 1-year nutritional outcomes of the SADS procedure. From October 2014 to January 2017, a total of 120 patients were enrolled at 6 sites across the U.S. and underwent the SADS procedure; WL, co-morbidities, QOL, and AEs were followed post-procedure for 12 months. At 1, 6, and 12 months, 98.3%, 85.5%, and 77.1% of the patients were available for assessment, respectively. At 12 months, patients showed significantly reduced BMI when compared to baseline (46.8 ± 5.8 versus 29.8 ± 4.4, $p < 0.001$ respectively); 65 patients had T2DM at baseline; however, 11 patients were lost to follow-up. Of the available data (54 patients), 96.3% of the patients had a resolution of T2DM by 12 months with a mean A1C reduction from 7.8 ± 1.6 to 5.3 ± 0.7.

Furthermore, there were reductions in hyperlipidemia, sleep apnea, and hypertension at 12 months. Patient GERD satisfaction and QOL (SF-36) scores were significantly higher at 12 months post-procedure ($p < 0.001$ in all cases) while 12-month protein levels remained at normal values. There were abnormalities of parathyroid hormone (PTH) and vitamin D at 1 year with all other nutritional markers being not significantly different at 1 year from baseline. There were 10, III-b or greater complications according to the Clavien-Dindo scoring system during the study period, not all of which were related to the surgery. The authors concluded that SADS was a highly effective WL procedure with significant co-morbidity reduction at 1 year. At 1 year, complications and vitamin and mineral deficits appeared to be consistent with other mal-absorption operations. The authors concluded that long-term follow-up is needed, especially around complications and vitamin deficiencies.

Torres et al. (2017) published a retrospective chart review of patients from their center receiving bariatric procedures, evaluating outcomes at 3-year follow-up.[90] Outcomes were evaluated separately for patients with and without diabetes. For patients without diabetes, comparisons were made among patients who underwent RYGB (n=149) or SADI-S (n=106). For patients with diabetes, comparisons were made among patients who underwent RYGB (n=97), biliopancreatic diversion/duodenal switch (BPD/DS) (n=77), or SADI-S (n=97). Among the patients without diabetes, significant differences favoring SADI-S over RYGB were found in percent excess weight loss; systolic blood pressure; total, HDL and LDL cholesterol; and insulin. Significant differences were not found in diastolic blood pressure or fasting glucose. Among the patients with type 2 diabetes, remission rates according to American Diabetic Association criteria were: 55%, 70%, and 76% for patients receiving RYGB, BPD/DS, and SADI-S, respectively. Patients with diabetes who underwent BPD/DS or SADI-S experienced significantly lower total cholesterol and triglyceride levels compared with those undergoing RYGB after 3 years of follow-up.

Stomach Intestine Pylorus Sparing Surgery (SIPS)

Neichoy et al (2018) performed a retrospective analysis on data from 225 patients who underwent a primary SIPS procedure by 2 surgeons at a single center.[91] Two hundred twenty-five patients were identified for analysis. The mean preoperative body mass index (BMI) was 52.4 ± 9.1 kg/m^2. Forty-eight patients were beyond 2 years after surgery, with data available for 30 patients (62.5% follow-up). Three patients were lost to follow-up. At 2 years, the patients had an average change in BMI of 26.6 U (kg/m^2) with an average of 88.7% of excess weight loss. Three deaths were related to the surgery. The most common short-term complication was a leak (2.2%), whereas the most common long-term complication was diarrhea (2.2%).

Cottam et al (2017) stated that in bariatric surgery, the procedure with the highest average weight loss is the bilio-pancreatic diversion with duodenal switch (BPDDS).[92] A new simplified duodenal switch called the SIPS surgery with less malabsorption and 1 fewer anastomosis claims to have similar outcomes when compared to the BPDDS. These researchers performed a retrospective matched cohort analysis of SIPS versus BPDDS patients in a single private practice by matching every BPDDS to a SIPS patient of the same gender and BMI. Excess weight loss (EWL) percentage, BMI, and percentage total weight loss (% TWL) were compared. Additionally, co-morbidity resolution, nutritional data, and complications were also compared. Data were analyzed using both descriptive and comparative statistics. Over 2 years, there was no statistical difference in weight loss between BPDDS and SIPS. There also was no difference in nutritional data between the 2 procedures pre- and post-op. Complication rates were lower in SIPS however, due to the small sample sizes this is not statistically significant. The authors concluded that weight loss and nutritional results between SIPS and

BPDDS were similar at 2 years. However, there are fewer complications with SIPS. The main drawbacks of this study were its retrospective design and small sample size.

Mitzman et al. (2016) also collected data from patients who underwent the SIPS procedure for analysis. Regression analyses were performed for all follow-up weight loss data.[93] One hundred twenty-three patients were available. One hundred two patients were beyond 1 year postoperative, with data available for 64 (62%followed up). The mean body mass index (BMI) was 49.4 kg/m^2. Two patients had diarrhea (1.6 %), four had abdominal hematoma (3.2 %), and one had a stricture (0.8 %) in the gastric sleeve. Two patients (1.6 %) were readmitted within 30 days. One patient (0.8 %) was re-operated due to an early postoperative ulcer. At 1 year, patients had an average change in BMI of 19 units (kg/m^2), which was compared to an average of 38 % of total weight loss or 72 % of excess weight loss. The authors concluded that the SIPS procedure had effective weight loss results.

Duodenojejunal Sleeve

Chen et al. (2024) performed a systematic review of 30 studies (N=1751) to assess the efficacy and safety of the duodenal-jejunal sleeve for treating obesity and T2DM.[94] At 12 months post-implantation, there was a reduction in BMI of 4.8 kg/m² (95% CI 4.1, 5.5), an EWL of 41.3% (95% CI 33.4%, 49.2%), and TWL of 13.1% (95% CI 10.1%, 16.0%). Significant reductions in HbA1c and fasting glucose were observed, with standardized mean differences of -0.72 (95% CI -0.95, -0.48) and -0.62 (95% CI -0.82, -0.42), respectively. However, these improvements in weight loss and glycemic control were only partially maintained after explantation. The pooled early removal rate was 19%, and the incidence of severe adverse events was 17%, including device migration (6%), gastrointestinal hemorrhage (4%), device obstruction (4%), and hepatic abscess (2%). Further research is needed to better understand the long-term efficacy and safety of this procedure, including its associated risks.

A prior meta-analysis of 5 RCTs found significantly greater short-term weight loss (12 to 24 weeks) with the use of duodenojejunal sleeve compared to medical therapy.[95] However, no significant differences in diabetes-related symptom reduction were observed between groups. All included RCTs featured small sample sizes and were deemed by the investigators to be at high risk of bias.

Intragastric Balloon Devices

Evidence includes RCTs,[96,97], a case series with long-term follow-up on 1 of the devices,[98,] and systematic reviews on various intragastric balloon (IGB) devices.[99-102] RCTs have found significantly better weight loss outcomes with IGB devices compared with sham treatment or LT alone. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. A large case series with follow-up up to 5 years has suggested that patients regain weight over time. Additional long-term follow-up data are needed. There are some adverse events, and in a minority of cases, these adverse events can be severe. The FDA wrote 2 letters in 2017 to health care providers, 1 warning of spontaneous balloon inflation and pancreatitis and the other reporting 5 unanticipated deaths occurring in 2016 to 2017 following the IGB procedure. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S. Health care providers are encouraged to monitor patients receiving IGBs.

Aspiration Therapy Device

The evidence consists of an RCT with 4 years of follow-up[103], and a small case series with up to 2 years of follow-up.[104] The RCT found significantly greater weight loss (measured several ways) with AT compared with LT at 1 year. Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal; however, only 15/111 initial AT patients completed the study through 4 years. In addition to a high degree of missing data, the PATHWAY study noted a potentially high degree of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years postgastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. The case series followed only 15 patients more than 1 year; at 2 years, study completers had not regained weight and instead had lost additional excess weight. The total amount of data on AT remains limited and additional studies need to be conducted before conclusions can be drawn about the long-term effects of treatment on weight loss, metabolism, safety, and nutrition.

Bariatric surgeries performed in 2 stages have been proposed as a treatment option, particularly for patients with “super-obesity” defined as a BMI greater than 50 kg/m2. The rationale for a 2-stage procedure is that the risk of an extensive surgery is prohibitive in patients who are extremely obese. Therefore, a procedure with low-risk (usually an SG) is performed first. After the patient loses some weight, thus lowering the surgical risk, a second more extensive procedure (eg, BPD) is performed.

REVISION BARIATRIC SURGERY

Clinical Context and Therapy Purpose

The purpose of revision bariatric surgery is to address complications of a procedure or a procedure that has failed. Severe GERD is one of the most common indications for revision surgery.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who have had bariatric surgery.

Interventions

The therapy being considered is revision bariatric surgery to address perioperative or late complications of a bariatric procedure, to address bariatric surgery that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band, or to address severe GERD refractory to medical treatment.

Comparators

Comparators of interest include standard medical care without revision surgery.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating revision bariatric surgery has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up of 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Ataya et al (2023) published a systematic review and meta-analysis of 817 patients (n=7 retrospective comparative studies) to assess the outcomes of revisional procedures, namely RYGB (413 patients) and one anastomosis gastric bypass (OAGB, 404 patients) following unsuccessful SG.[105] OAGB resulted in greater weight loss than RYGB, with a mean difference of -5.84 (95% CI, -6.74 to -4.94; p<.00001; I^2=0%), greater total weight loss, and a higher diabetes remission rate (OR, 0.32; 95% CI, 0.14 to 0.71). However, OAGB was associated with a significantly higher incidence of postoperative GERD than RYGB (52 vs. 31: OR, 0.40; 95% CI, 0.24 to 0.67; p=.0005; I^2=0%).

Matar et al (2021) published a systematic review of 556 patients (n=17 studies) who underwent RYGB for SG-related complications, including GERD (30.4% cases) and insufficient weight loss and weight regain (52% of cases).[106] The mean BMI at the time of conversion ranged from 33.3 to 48.3 kg/m2. The pooled baseline BMI at conversion was 38.5 kg/m2 (95% CI, 36.49 to 40.6), at 6 months was down to 28.6 kg/m2 (95% CI, 16.1 to 41.0), and after 1 year was up to 32.1 kg/m2 (95% CI, 25.50 to 38.7). The pooled mean %TWL after completion of treatment was 25.2% (95% CI, 12.8 to 37.5) at 6 months and 22.8% (95% CI, 13.5 to 32.1) at 1 year. There was a 16.4% complication rate at 30 days, which decreased to 11.4% after 30 days. At 1-year post RYGB, the rate of resolution for common comorbidities was as follows: GERD, 79.7% (95% CI, 59.6 to 91.3); T2D, 57.7% (95% CI, 36.9 to 76.1); and hypertension, 49.4% (95% CI, 25.8 to 73.3).

Parmar et al (2020) published a systematic review of 1075 patients (n=17 studies) who underwent one OABG as a revisional bariatric procedure after failure of a primary LAGB and SG.[107] No RCTs were available on this topic and no meta-analyses were performed as part of this systematic review. The most commonly reported reason for revisional surgery was poor response (81%) followed by gastric band failure (35.9%), GERD (13.9%), intolerance (12.8%), staple line disruption (16.5%), pouch dilatation (17.9%), and stomal stenosis (10.3%). Results revealed that after the revisional OABG , the mean percent EWL was 50.8% at 6 months, 65.2% at 1 year, 68.5% at 2 years, and 71.6% at 5 years. Resolution of comorbidities after OAGB- was significant with 80.5% of patients with T2D, 63.7% of patients with hypertension, and 79.4% of patients with reporting resolution. The overall readmission rate following OAGB was 4.73%, the mortality rate was 0.3%, and the leak rate was 1.54%. Although the authors concluded that OAGB is a safe and effective choice for revisional bariatric surgery, RCTs on this topic are needed as currently only retrospective cohort studies with heterogenous data are available.

Brethauer et al (2014) conducted a systematic review of reoperations after primary bariatric surgery for the American Society for Metabolic and Bariatric Surgery that included 175 studies, most of which were single-center retrospective reviews.[149] The review is primarily descriptive, but made the following conclusions: “The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise.”

Nonrandomized Studies

A retrospective study reported by Dang et al (2023) analyzed serious complications and mortality in patients who underwent revision surgery (conversion of SG to RYGB, N= 13,432) or primary RYGB (N=84,543) in 2020 and 2021.[108] GERD was the most common indication for revision (55.3%), followed by weight regain (24.4%), and inadequate weight loss (12.7%). Revisional RYGB after SG was associated with a higher rate of serious complications than primary RYGB (7.2% vs. 5.0%, p<.001). There was no significant difference in 30-day mortality.

Petrucciani et al (2021) published a retrospective analysis of 215 patients who underwent revisional OAGB with a biliopancreatic limb of 150 cm after failing LAGB at a single center between 2010 and 2016.[109] The indication for surgery was weight loss failure in 30.7% of cases and long-term complications in the remaining cases. The mean BMI at the time of OAGB was 42 kg/m2. At 2 years after OAGB, 9.7% of patients were lost to follow-up, BMI was down to 28 ± 5.5 kg/m2, %EWL was 88.2 ± 23.9, and %TWL was 38.7 ± 9.3. At 5 years after OAGB, 16.6% of patients were lost to follow-up, BMI was slightly up to 29.2 ± 5.8 kg/m2, %EWL was 82.4 ± 25, and %TWL was 36.1 ± 10. Overall postoperative morbidity was 13.5% with a 5.9% rate of postoperative abscess with or without staple line leak. Treatment-resistant occurred in 21.3% of patients; conversion to RYGB was required in 4.2% of cases.

Sudan et al (2015) reported on safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database.[110] The Bariatric Outcomes Longitudinal Database was a large, multi-institutional bariatric surgery–specific database to which data were submitted from 2007 through 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence program. Surgeries were classified as primary or reoperative bariatric. Reoperations were further divided into corrective surgeries (when complications or incomplete treatment effect of a previous bariatric operation was addressed, but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy). Of 449,473 bariatric operations in the database, 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3%) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective and 8750 (30.5%) were conversions. The primary bariatric operations were RYGB (n=204,705 [49.1%]), LAGB (n=153,142 [36.5%]), SG (n=42,178 [10%]), and BPD-DS (n=4260 [1%]), with the rest classified as miscellaneous. LAGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to RYGB). Compared with primary operations, mean hospital length of stay was longer for corrections (2.04 days vs. 1.8 days, p<.001) and for conversions (2.86 days vs. 1.8 days, p<.001). Mean percent EWL at 1 year was 43.5% after primary operation, 39.3% after conversions, and 35.9% after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions (0.31%) than for primary surgeries (0.17%; p<.001), with no statistically significant difference for corrections (0.24%) compared with primary surgeries (0.17%; p=not significant [NS]). One-year serious adverse event rates were higher for conversions (3.61%) than for primary operations (1.87%; p<.001), with no statistically significant difference for corrections (1.9%) compared with primary operations (1.87%; p=NS). The authors concluded that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

Endoscopic Revision Procedures

While bariatric surgery revision or correction can be conducted using standard surgical approaches, novel endoscopic procedures are being developed. Some procedures use devices also being evaluated for the endoscopic treatment of GERD. The published data on the use of these devices for treatment of regained weight is limited. Published case series have reported results using a number of devices and procedures (including sclerosing injections) as a treatment for this condition. The largest series (2007) found involved 28 patients treated with a sclerosing agent (sodium morrhuate).[111] Reported trials that used 1 of the suturing devices had fewer than 10 patients. For example, Herron et al (2008) reported on a feasibility study in animals.[112] Thompson et al (2006) reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who regained weight and had dilated gastrojejunal anastomoses after RYGB.[113] No comparative trials were identified; comparative trials are important because of the known association between an intervention and short-term weight loss.

The StomaphyX device, which has been used in this approach, was cleared by FDA through the 510(k) process. It was determined to be equivalent to the EndoCinch system, which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal tract surgery. Eid et al (2014) reported on results from a single-center RCT that compared the StomaphyX device with a sham procedure for revisions in patients with prior weight loss after RYGB at least 2 years earlier.[114] Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow-up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group because preliminary analysis failed to achieve the primary efficacy endpoint in at least 50% of StomaphyX patients. The primary 12-month efficacy endpoint (reduction in pre-RYGB excess weight by ≥15%, excess BMI loss, and BMI <35 kg/m2) was achieved by 10 (22.2%) of 45 in the StomaphyX group and 1 (3.4%) of 29 in the sham control group (p<.01).

A 2009 survey of American Society for Metabolic and Bariatric Surgery members (bariatric surgeons) indicated different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures.[57] The surgeons were “willing to accept less weight loss and more risk for revisional endoluminal procedures than for primary endoluminal procedures.” The durability of the procedures was a concern, and most surgeons were unwilling to consider the procedures until their efficacy has been proven. A 2013 systematic review of studies reporting outcomes after endoluminal revision of primary bariatric surgery conducted by the American Society for Metabolic and Bariatric Surgery concluded: “The literature review shows the procedures on the whole to be well tolerated with limited efficacy. The majority of the literature is limited to small case series. Most of the reviewed devices are no longer commercially available."[115]

Cohen et al (2019) conducted a systematic review evaluating the safety and efficacy of endoscopic gastroplasty for medically uncontrolled obesity.[116] Nine observational studies and a single RCT were identified by the authors. Follow-up duration in the majority of studies was limited to 6 to 12 months with several studies reporting high rates of loss to follow-up. Percent total body weight loss ranged from -15.1% to 19.5%. Reduction in BMI ranged from -1.69 to -7.5 kg/m2. Serious adverse events ranged from 2% to 10%. The quality of the current evidence was graded very low to moderate, with limited long-term data on weight loss durability and procedure safety.

Section Summary: Revision Bariatric Surgery
Systematic reviews and case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss and reduced comorbidities including GERD. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. A large retrospective analysis found a serious complication rate of 7.2% for conversion to RYGB in 13,432 individuals and no difference in 30-day mortality compared to primary RYGB.

Bariatric Surgery in Adolescents

Clinical Context and Therapy Purpose

The purpose of bariatric surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in individuals who are adolescents with obesity.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who are adolescents with obesity. While guidelines for bariatric surgery in adolescents are not uniform, most use weight-based criteria that parallel those for adults.

Interventions

The therapy being considered is open or laparoscopic gastric bypass, laparoscopic adjustable gastric banding, or open or laparoscopic sleeve gastrectomy.

Comparators

Comparators of interest include standard medical care. Treatment for adolescent children with obesity includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes

The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating gastric bypass, LAGB, or SG as a treatment for obesity has varying lengths of follow-up, ranging from 1 to 6 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Bariatric Surgery Techniques in Adolescents

Review of Evidence

Systematic Reviews

Oei et al (2024) conducted a systematic review and meta-analysis on bariatric surgery for managing pediatric obesity, focusing on patient-reported outcome measures, cardiometabolic risk factors, anthropometry, and adverse events (AEs) (Table 7).[117] This review was undertaken in support of the Canadian Clinical Practice Guideline for Managing Pediatric Obesity. The review included studies through January 2022, comprising RCTs and observational studies with reported baseline ages from 10 to 21 years old (mean <18 years old) and participants with baseline BMI values from 38.5 to 66.2 kg/m2. Of the 63 eligible publications, 43 were original studies (N=6128 participants, 66% female). Six surgical techniques were evaluated, mostly through uncontrolled observational studies. Short-term follow-up (<18 months) was common. Surgery significantly improved health-related quality of life, cardiometabolic risk factors, and body mass index Z-score (BMIz) compared to baseline. Mild or non-specific AEs were reported, with serious AEs being rare.

Qi et al (2017) published a systematic review and meta-analysis on the use of bariatric surgery for the treatment of adolescents with obesity (Table 7).[118] In a literature search conducted through July 2017, 49 studies were identified for inclusion. Study quality was assessed using the Newcastle-Ottawa Scale. Age of patients ranged from 14 to 20 years. BMI ranged from 34 to 63 kg/m2. Overall results showed significant improvements in BMI as well as glycemic and lipid control with various bariatric surgery techniques. RYGP showed the largest improvements compared with other procedures, with LAGB and SG also showing improvements in this population.

In a systematic review of 23 studies, Black et al (2013) concluded that the available literature demonstrated a high rate of significant short-term weight loss after bariatric surgery (Table 7).[119] The literature search was conducted through January 2013. Quality assessment of the included studies was not discussed. Ages of patients at the time of surgery ranged from 5 to 23 years. A meta-analysis showed significant reductions in BMI. Meta-analyses were not conducted on the resolution of comorbidities due to heterogeneity in reporting. However, most cases of hypertension, OSA, T2D, and dyslipidemia were reported to have resolved at 1-year follow-up. Reviewers noted that complication and comorbidity rates were not well-defined.

Treadwell et al (2008) conducted a systematic review and meta-analysis of the published evidence on bariatric surgery in adolescents (Table 7).[120] Their analysis included English-language articles on currently performed procedures when data were separated by procedure, and there was a minimum 1-year follow-up for weight and BMI. Studies must have reported outcomes data for 3 or more patients ages 21 years or younger, representing at least 50% of pediatric patients enrolled at that center. Nineteen studies reported on between 11 and 68 patients who were 21 years or younger. Eight studies of LAGB (mean BMI, 45.8 kg/m2; median age range, 15.6 to 20 years); 6 studies on RYGB (mean BMI, 51.8 kg/m2; median age range, 16 to 17.6 years); 5 studies of other procedures (mean BMI, 48.8 kg/m2; median age range, 15.7 to 21 years) were included.

Meta-analyses of BMI at longest follow-up indicated sustained and clinically significant reductions for both LAGB and RYGB (Table 8). Comorbidity resolution was sparsely reported, but surgery appeared to resolve some medical conditions, including diabetes and hypertension; 2 studies of LAGB showed large rates of diabetes resolution but low patient

enrollment, and only 1 study of RYGB reported relevant data. No in-hospital or postoperative deaths were reported in any LAGB study. The most frequently reported complications for LAGB were band slippage and micronutrient deficiency with sporadic cases of band erosion, port/tube dysfunction, hiatal hernia, wound infection, and pouch dilation. More severe complications were reported for RYGB, such as pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition. No in-hospital deaths were reported; however, 1 patient died 9 months after the study with severe Clostridium difficile colitis; 3 others died of causes not likely to have been directly related to the bariatric surgeries. No LAGB studies reported data on the impact of surgery on growth and development. One study of RYGB reported pre- and postoperative heights and concluded that there was no evidence of growth retardation at an average follow-up of 6 years, but it could not be determined from the data whether expected growth was achieved.

Table 7. Systematic Review Characteristics for Bariatric Surgery for Adolescents with Obesity

Study (Year)	Dates	Studies	Participants	Design	Duration
Oei et al (2024)	Jan 2022	63	6128	1 RCT 13 controlled 49 uncontrolled	short (<18 months); intermediate (18–24 months); long-term (>24 months)
Qi et al (2017)	Jul 2017	49	RYGP: 1216 LABG: 1028 LSG: 665 Other: 98	1 RCT 22 prospective 26 retrospective	12-120 mo
Black et al (2013)	Jan 2013	23	RYGP: 256 LAGB: 271 LSG: 90 Other: 20	• 1 controlled • 22 uncontrolled	6-120 mo
Treadwell et al (2008)	Dec 2007	18	RYGB: 131 LAGB: 352 Other: 158	• 1 prospective • 17 retrospective	NR

LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectromy; NR: not reported; RYGP: Roux-en-Y gastric bypass

Table 8. Systematic Review Results for Bariatric Surgery for Adolescents with Obesity

Study (Year)	BMI Reduction Mean Difference (95% CI)	Fasting Blood Insulin, mIU/L Mean Difference (95% CI)	Total Cholesterol, mg/dL Mean Difference (95% CI)
Oei et al (2024)			
RYGP	-11.2 (-13.3 to -9.1)	-106.9 (-118.1 to -95.7)	NR
LAGB	-6.4 (-8.1 to -4.6)	-86.5 (-101.8 to -72.3)	-0.1 (-0.2 to 0.1)
LSG	-12.2 (-13.7 to -10.7)	-87.5 (-106.9 to -68.2)	-0.2 (-0.4 to -0.1)
Mixed	-7.0 (-9.3 to -4.7)	-73.3 (-97.7 to -47.8)	-0.1 (-0.3 to 0.1)
Qi et al (2017)			
RYGP	18.5 (16.4 to 20.7)	24.8 (10.0 to 30.7)	29.4 (18.1 to 40.7)
LAGB	12.1 (11.0 to 13.3)	20.5 (16.4 to 24.6)	2.2 (-10.0 to 14.4)
LSG	16.0 (13.2 to 20.7)	18.4 (11.4 to 25.3)	13.6 (2.9 to 24.2)
Other	23.2 (15.6 to 30.7)	28.3 (5.7 to 50.9)	49.5 (29.9 to 69.2)
Black et al (2013)			
RYGP	17.2 (14.3 to 20.1)	NR	NR
LAGB	10.5 (9.1 to 11.8)	NR	NR

LSG	14.5 (11.7 to 17.3)	NR	NR
Other	NR	NR	NR
Treadwell et al (2008)			
RYGP	(17.8 to 22.3)[a]	NR	NR
LAGB	(10.6 to 13.7)[a]		

BMI: body mass index; CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; NR: not reported; RYGP: Roux-en-Y gastric bypass, a Short-term FU (<18 months); b Intermediate FU (18-24 months); c Long-term FU (>24 months); d Measured as pmol/L; e Measured as mmol/L; f No point estimate provided, only 95% CIs given.

Randomized Controlled Trials

Roebroek et al (2024) conducted a single-center RCT designed to assess one-year health effects of bariatric surgery in 59 adolescents aged 14 to 16 years with severe obesity (BMI ≥40 kg/m2, or ≥35 kg/m2 in combination with comorbidity).[121] Participants were assigned to multidisciplinary lifestyle intervention (MLI) combined with LAGB (n=29) versus only MLI (n=30). Main outcomes were weight change and sex- and age-specific BMI loss. Additionally, glucose metabolism, blood pressure and lipid profile were analyzed. Mean (±SD) weight loss in the surgery group was 11.2 ± 7.8% after 12 months, compared to a weight gain of 1.7 ± 8.1% in the control group. The fasting insulin, insulin resistance score and lipid profile improved significantly in the surgery group. There is a need to further assess the evidence on safety and long-term efficacy of LAGB in this study population.

Section Summary: Bariatric Surgery Adolescents

Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy

Several systematic reviews and meta-analyses on bariatric surgery for adolescents with obesity found overlaps among studies, primarily assessing gastric bypass, SG, and LAGB. A recent meta-analysis indicated improved health-related quality of life, cardiometabolic risk factors, and BMI. An RCT reported significant weight loss and metabolic improvements with LAGB compared to conservative treatment. Adolescent outcomes in percent EWL and BMI change are similar to adults, though concerns about developmental maturity, psychosocial status, and informed consent are greater.

Bariatric Surgery Other Than Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy

There is less evidence for the use of bariatric techniques other than gastric bypass, LAGB, and SG. Sample sizes are small for these other techniques and meta-analyses have shown wide CIs in the estimates.

Guideline recommendations for bariatric surgery in adolescents lack uniformity but generally correspond to the clinical selection criteria for adults and supplement these clinical selection criteria with greater attention to issues of maturity and psychosocial status.

Bariatric Surgery in Preadolescent Children

Review of Evidence

Systematic Reviews

Black et al (2013; described above) published a systematic review of 23 studies on bariatric surgery in children and adolescents.[119]

Shah et al. (2024) conducted an analysis of surgical outcomes in preteens versus teens using data from the American College of Surgeons-Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database.[122] Among the 4755 patients identified, 47 were <13 years old. The study found that preteens had a similar BMI (46.9 ± 7 vs. 47 ± 13 kg/m2) to their teenage counterparts. Preteens were more prone to sleep apnea and TD2M. Notably, preteens experienced no complications compared to teens and had no unplanned readmissions (0% vs. 2.9%) or reoperations (0% vs. 0.8%) within 30 days post-surgery. Furthermore, there were no mortalities among preteens (0% vs. 0.1%). The risk-adjusted decrease in BMI between preteens and teens was similar at the 30-day mark (4.2 [95% CI: 3.0 to 5.4] vs. 4.6 [95% CI: 4.4 to 4.7], p=.6). For preteens, the decrease in BMI was 7 ± 3 kg/m2 at 3 months and 9 ± 4 kg/m2 at 12 months post-surgery, translating to a percentage BMI change of 16 ± 7 and 20 ± 8, respectively.

Nonrandomized Studies

Alqahtani et al (2021), described above, included children as young as 5 years of age in their prospective, noncomparative cohort study analyzing durability of weight loss and comorbidity resolution, growth velocity, and adverse events associated with LSG in children and adolescents with severe obesity over 10 years.[123] In the 5- to 14-year age group, 801 (32%) children were included. The mean percent of 95th percentile at baseline for children in this age group was 177% ± 38%. The %EWL after LSG in children aged 5 to 14 years was not significantly different from the adolescent children (>14 years) as results were consistent across age groups. Additionally, the height z-score change did not differ in this age group, indicating no impact on change over 10 years of follow-up.

Section Summary: Bariatric Surgery in Preadolescent Children

There is a scarcity of published data, and no studies have been identified that specifically focus on bariatric surgery in preadolescent children. However, a recent prospective noncomparative cohort study by Alqahtani et al (2021) has shown significant, long-term (follow-up of 10 years) weight loss and resolution of comorbidities without safety concerns following LSG in children as young as 5 years old (32% of children were between the ages of 5 and 14 at the time of surgery). Additionally, a recent analysis of surgical outcomes in preteens versus teens, using data from the American College of Surgeons-Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database, demonstrated that bariatric surgery in preteens is both safe and effective when performed at specialized centers. Nonetheless, further comparative studies are required to draw definitive conclusions about the net health benefits of bariatric surgery in preadolescent children with obesity.

Hiatal Hernia Repair in Conjunction With Bariatric Surgery for Adults with Class 3 Obesity and a Preoperative Diagnosis of Hiatal Hernia

Clinical Context and Therapy Purpose

The purpose of hiatal hernia repair with bariatric surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as standard medical care, in patients with class 3 obesity and a preoperative diagnosis of hiatal hernia.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with class 3 obesity and a preoperative diagnosis of hiatal hernia.

Interventions
The therapy being considered is hiatal hernia repair with bariatric surgery.

Comparators
Comparators of interest include standard medical care. Treatment for patients with class 3 obesity and a preoperative diagnosis of hiatal hernia includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are OS, change in disease status, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity.

The existing literature evaluating hiatal hernia repair with bariatric surgery as a treatment for class 3 obesity and a preoperative diagnosis of hiatal hernia has varying lengths of follow-up, ranging from 1 to 3 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. One-year follow-up is necessary to demonstrate weight loss efficacy. Longer follow-up to 5 to 10 years is desirable to assess maintenance of weight loss, impact on co-occurring conditions, and appearance of long-term complications.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Hiatal hernia is associated with obesity, and existing hiatal hernias may be worsened with bariatric surgery. In some studies, the presence of a hiatal hernia has been associated with complications after LAGB.[124] Although other studies have reported no differences in perioperative complications after LAGB in patients with and/or a hiatal hernia or those without and/or hiatal hernia.[125] Hiatal hernias, either incidentally found at surgery or diagnosed preoperatively, are often repaired at the time of bariatric surgery. In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the management

of hiatal hernia, recommending that, during RYGB, SG, and the placement of LAGBs, all detected hiatal hernias should be repaired (grade of recommendation: weak; evidence quality moderate).[126] There is limited evidence regarding whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists primarily of cohort studies comparing outcomes for patients who had a hiatal hernia and underwent repair during bariatric surgery with patients without a hiatal hernia.

Systematic Reviews

Chen et al (2021) published a systematic review of 18 studies that evaluated outcomes after hiatal hernia repair plus SG in obese patients (N=937).[127] Results demonstrated that patients who underwent hiatal hernia repair during SG (concomitant approach) had significant reductions in BMI (MD, -11.42 kg/m2, 95% CI, -12.8 to -10.03), and the risk of symptoms (OR, 0.20; 95% CI, 0.10 to 0.41) and esophagitis (OR, 0.12; 95% CI, 0.05 to 0.26). Hiatal hernia repair during SG was superior to SG alone for remission (OR, 2.97; 95% CI, 1.78 to 4.95), but not de novo (OR, 0.61; 95% CI, 0.24 to 1.53). The pooled recurrence rate for hiatal hernia after hiatal hernia repair plus SG was 11% (95% CI, 4 to 19).

Malaussena et al (2024) conducted a meta-analysis of 27 studies to determine the optimal surgical approach for bariatric patients with hernias.[128] The study evaluated three options for ventral hernia repair in these patients: a staged approach where bariatric surgery precedes definitive hernia repair (BS-first), a staged approach where hernia repair precedes bariatric surgery (HR-first), or a concomitant approach. Seven comparative studies were included, with 8548 staged patients (6458 BS-first) and 3528 concomitant patients. Additionally, 7 single-arm staged studies and 13 single-arm concomitant studies were analyzed. The concomitant approach was found to reduce the odds of surgical site infections, reoperation, and seromas. Conversely, the staged approach (BS-first) was associated with a lower risk of mesh infection. The single-arm studies indicated that hernia recurrence was less frequent with the staged BS-first approach compared to the concomitant approach. These findings suggest that a concomitant approach is suitable for hernias not requiring mesh, whereas the staged (BS-first) approach is preferable for hernias requiring mesh placement.

Section Summary: Hiatal Hernia Repair in Conjunction With Bariatric Surgery for Adults with Obesity and a Preoperative Diagnosis of Hiatal Hernia

Hiatal hernia repair is frequently undertaken at the time of bariatric surgery. The evidence related to whether hiatal hernia repair improves outcomes after bariatric surgery is limited, particularly for hiatal hernias that are incidentally diagnosed at the time of surgery. For patients with a preoperative diagnosis of a hiatal hernia, symptoms related to a hernia, and indications for surgical repair, it is reasonable to undertake this procedure at the time of bariatric surgery. For other patients, it is uncertain whether repair of a hiatal hernia at the time of bariatric surgery improves outcomes. A systematic review found that hiatal hernia repair during SG was superior to SG alone for remission, but not de novo. This combined approach of hernia repair during bariatric surgery has also been shown in a meta-analysis to significantly lower the risk of surgical site infections, reoperations, and seromas.

Esophagogastroduodenoscopy with Bariatric Surgery

Clinical Context and Test Purpose

Esophagogastroduodenoscopy (EGD) has been proposed to serve several roles in bariatric surgery, serving functions across preoperative, intraoperative, and postoperative stages.

Before the surgery, EGD is employed to detect any preexisting gastrointestinal conditions that might influence the surgical approach or require plan adjustments. During the operation, EGD assists the surgeon in positioning instruments accurately and identifying any immediate complications. After the surgery, EGD is used for monitoring the healing process, identifying complications such as leaks or strictures, and addressing any new symptoms or concerns.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals undergoing a EGD either prior to, during or after bariatric surgery of any form.

Interventions
The therapy being considered is EGD before, during, and after bariatric surgery.

Comparators
Comparators of interest may include other diagnostic procedures used to evaluate the gastrointestinal tract. These can include imaging studies such as upper gastrointestinal series, CT scans, and MRI. Additionally, other endoscopic techniques like capsule endoscopy and endoscopic ultrasound may be considered when assessing the structure and function of the esophagus, stomach, and duodenum. Each of these alternatives has specific indications and limitations, and the choice of procedure will depend on the patient's specific medical condition and the surgeon's assessment.

Outcomes
The general outcomes of interest are overall survival, change in disease status, health status measures, surgical outcomes, functional outcomes, quality of life, and test validity.

Before the surgery, EGD is employed to detect any preexisting gastrointestinal conditions that might influence the surgical approach or require plan adjustments.

- Clinical validity: EGD accuracy in detecting preexisting conditions that influence surgical decisions
- Clinical utility: Surgical outcomes (immediate and delayed); quality of life

During the operation, EGD assists the surgeon in positioning instruments accurately and identifying any immediate complications.

- Clinical validity: EGD accuracy in assisting in positioning and identifying complications
- Clinical utility: Surgical outcomes (immediate and delayed); quality of life

After the surgery, EGD is used for monitoring the healing process, identifying complications such as leaks or strictures, and addressing any new symptoms or concerns.

- Clinical validity: EGD accuracy in detecting delays in healing, complications and new symptoms
- Clinical utility: Surgical outcomes (long term); functional outcomes; quality of life

Study Selection Criteria
For the evaluation of the clinical validity of the tests included in this review, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology
- Included a suitable reference standard. The standard for evaluation is clinical assessment. The decision to conduct an EGD is made at the surgeon's discretion. For instance, the ASMBS advises that the use of EGD should be selective and based on the presence of relevant symptoms.
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse). Please see above outcomes section.

Review of Evidence
Muir et al (2023) conducted the most comprehensive systematic review and meta-analysis to date, incorporating 47 observational studies and assessing a total of 23,368 patients.[129] Notably, 20% of these patients had findings from EGD that either altered their operative management or postponed their bariatric surgery. Although the heterogeneous nature of the reporting in the included studies precluded a meta-analysis of the specific causes for these findings, the most frequently reported conditions were gastritis, hiatus hernia, and esophagitis. The remaining 80% of patients who underwent preoperative EGD saw no changes to their surgical plans or delays in their surgery due to the procedure. Similar results have been reported in previous systematic reviews regarding the proportions of patients in whom EGD did not impact management.[130] There is a need for direct, comparative, homogenous studies assessing whether EGD should be routine before bariatric surgery, and whether it is judicious to expose many patients to an invasive procedure that has potential risk and insufficient evidence of effectiveness.

The ASMBS (2021) conducted a literature review on the significance of preoperative EGD for patients considering bariatric surgery.[131] This review aimed to support the ASMBS's position statement on the necessity of upper gastrointestinal endoscopy both before and after bariatric surgery (see Practice Guidelines and Position Statements section). The review identified 28 studies that assessed the role of endoscopy in patients, whether symptomatic or asymptomatic, before undergoing bariatric surgery. These studies collectively included 12,385 patients, with an average age of 44 years, 68% of whom were female, and an average BMI of 45.9 kg/m² (ranging from 40.6 to 50.1 kg/m²). The analysis revealed that 27% of all patients seeking bariatric surgery were diagnosed with GERD. Among patients, regardless of gastrointestinal symptoms, the prevalence of hiatal hernia, erosive esophagitis, and Barrett's esophagus was 21%, 16%, and 3%, respectively. Furthermore, 35% of patients had at least one abnormal finding during endoscopy. Notably, among those seeking bariatric surgery without any gastrointestinal or GERD symptoms, the detection rates for hiatal hernia, erosive esophagitis, and Barrett's esophagus were 17%, 17%, and 1%, respectively.

Clinical Utility
Evidence supporting the clinical utility of EGD in bariatric surgery is limited. Current research primarily addresses the pre-operative use of EGD, with systematic reviews revealing that only one-fifth of patients had EGD findings that influenced their operative management or delayed their surgery. The scope of EGD's utility in intraoperative and postoperative contexts remains underexplored. Direct evidence of EGD's clinical benefits in bariatric surgery is lacking, and its

use is generally based on clinical judgment and individual patient considerations. Currently, a complete evidence chain is absent due to insufficient information regarding clinical validity.

Section Summary: Esophagogastroduodenoscopy with Bariatric Surgery
Current research has focused on pre-operative utility of EGD. The evidence evaluating the scope of EGD in both intraoperative and postoperative settings is lacking in comparison. Systematic reviews have found that only one-fifth of patients had findings from EGD that either altered their operative management or postponed their bariatric surgery. There is a need for direct, comparative, homogenous studies assessing whether EGD should be routine before bariatric surgery, and whether it is judicious to expose many patients to an invasive procedure that has potential risk and insufficient evidence of effectiveness.

SUMMARY OF EVIDENCE

Adults with Class 3 Obesity

For individuals who are adults with class 3 obesity (body mass index [BMI] ≥40kg/m2) who are treated with bariatric surgery using open or laparoscopic gastric bypass using a Roux-en-Y, laparoscopic adjustable gastric banding, open or laparoscopic sleeve gastrectomy, or open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Evidence from nonrandomized comparative studies, and meta-analyses of RCTs has consistently reported that bariatric surgery results in substantially greater weight loss than nonsurgical therapy. Data from the largest comparative study (the Swedish Obese Subjects (SOS) study) found that bariatric surgery was associated with improvements in mortality, type 2 diabetes (T2D), cardiovascular risk factors, and quality of life. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adults with Class 2 Obesity

For individuals who are adults with class 2 obesity (BMI ≥35 to 39.9 kg/m2) who are treated with bariatric surgery using open or laparoscopic gastric bypass using a Roux-en-Y, laparoscopic adjustable gastric banding, open or laparoscopic sleeve gastrectomy, or open or laparoscopic biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Evidence from nonrandomized comparative studies, and meta-analyses of RCTs has consistently reported that bariatric surgery results in substantially greater weight loss than nonsurgical therapy. Data from the largest comparative study (the SOS study) found that bariatric surgery was associated with improvements in mortality, T2D, cardiovascular risk factors, and quality of life. Additionally, bariatric surgery may greatly reduce the risk of cancer in individuals with obesity and diabetes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adults with Class 1 Obesity and Type 2 Diabetes

For individuals who have Class 1 obesity (BMI ≥30 to 34.9 kg/m2) and T2D with bariatric surgery using open or laparoscopic gastric bypass using a Roux-en-Y, laparoscopic adjustable gastric banding, open or laparoscopic sleeve gastrectomy, or open or laparoscopic

biliopancreatic bypass/diversion (i.e., Scopinaro procedure) with duodenal switch, the evidence includes systematic reviews of RCTs and observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in adults with obesity, including those with a BMI between 30 and 34.9 kg/m2. The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The quality of evidence (GRADE) from both RCTs and observational studies for complete diabetes remission and BMI changes was consistently rated as low to very low across various follow-up periods. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 5 years of follow-up data.

Adults with a Body Mass Index <35 kg/m2 Who Do Not Have Type 2 Diabetes

For individuals with a BMI <35 kg/m2 who do not have T2D who receive bariatric surgery, the evidence includes systematic reviews of RCTs and observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A few small RCTs and case series have reported a loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Revision Bariatric Surgery

For individuals who are adults who receive revision bariatric surgery, the evidence includes systematic reviews, case series, and registry data. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews and case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss and reduced comorbidities including gastroesophageal reflux disease. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. A large retrospective analysis found a serious complication rate of 7.2% for conversion to Roux-en-Y gastric bypass in 13,432 individuals and no difference in 30-day mortality compared to primary Roux-en-Y gastric bypass. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Adolescents with Obesity

For individuals who are adolescent children with obesity who are treated with bariatric surgery using open or laparoscopic gastric bypass, laparoscopic adjustable gastric banding, or open or laparoscopic sleeve gastrectomy, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of studies on bariatric surgery in adolescents, who mainly received gastric bypass or laparoscopic adjustable gastric banding or sleeve gastrectomy, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. A single-center small RCT reported significant weight loss and metabolic improvements with laparoscopic adjustable gastric banding compared to conservative treatment. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies

have generally reported that weight loss and reduction in risk factors for adolescents are similar to that for adults. Most experts and clinical practice guidelines have recommended that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a BMI greater than 50 kg/m2. Also, greater consideration should be placed on the patient developmental stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the patient can provide fully informed consent. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Preadolescent Children with Obesity

For individuals who are preadolescent children with obesity who receive bariatric surgery, there are no studies focused solely on this population. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. No studies have been identified that specifically focus on bariatric surgery in preadolescent children. However, a recent prospective noncomparative cohort study has shown significant, long-term (follow-up of 10 years) weight loss and resolution of comorbidities without safety concerns following LSG in children as young as 5 years old. Additionally, a recent analysis of surgical outcomes in preteens versus teens, using data from the American College of Surgeons-Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database, demonstrated that bariatric surgery in preteens is both safe and effective when performed at specialized centers. Nonetheless, further comparative studies are required to draw definitive conclusions about the net health benefits of bariatric surgery in preadolescent children with obesity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Hiatal Hernia Repair with Bariatric Surgery

For individuals with obesity and a preoperative diagnosis of a hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes a systematic review, cohort studies, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review found that hiatal hernia repair during sleeve gastrectomy was superior to sleeve gastrectomy alone for gastroesophageal reflux disease remission, but not de novo. This combined approach of hernia repair during bariatric surgery has also been shown in a meta-analysis to significantly lower the risk of surgical site infections, reoperations, and seromas. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of a hiatal hernia has been present, repairing the hiatal hernia during bariatric surgery resulted in fewer complications. However, the results are limited to individuals with a preoperative diagnosis. There was no evidence on the use of hiatal hernia repair when the hiatal hernia diagnosis is incidental. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Esophagogastroduodenoscopy with Bariatric Surgery

For Individuals with obesity undergoing bariatric surgery who receive esophagogastroduodenoscopy (EGD), the evidence includes systematic reviews of observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Current research has focused on pre-operative utility of EGD. The evidence evaluating the scope of EGD in both intraoperative and postoperative settings is lacking in comparison. Systematic reviews have found that only one-fifth of patients had findings from EGD that either altered their operative management or postponed their bariatric surgery. There is a need for direct comparative homogenous studies assessing whether EGD should be

routine before bariatric surgery, and whether it is judicious to expose many patients to an invasive procedure that has potential risk and insufficient evidence of effectiveness. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06200961	Use of Sedation-Free Transnasal Endoscopy to Improve Access and Lower Costs of Endoscopic Evaluations in a Bariatric Medical and Surgical Program	100	Dec 2025
NCT02390973[a]	Surgery Versus Best Medical Management for the Long Term Remission of Type 2 Diabetes and Related Diseases (REMISSION)	408	Mar 2029
NCT02328599	A Prospective Consortium Evaluating the Long-term Follow-up of Patients With Type 2 Diabetes Enrolled In a Randomized Controlled Trial Comparing Bariatric Surgery Versus Medical Management (ARMMS-T2D)	302	Jun 2024
NCT03610256	Prospective Multicentric Randomized Trial Comparing the Efficacy and Safety of single anastomosis- Duodeno Ileal Bypass With Sleeve Gastrectomy (SADI-S) Versus Roux-en-Y Gastric Bypass (RYGB) (SADISLEEVE)	382	Oct 2023 (active, not recruiting)
NCT03517072	Determinants of the Long-Term Success of Bariatric Surgery	1000	Jan 2024
NCT03472157	Prospective Multicentric, Open Label, Randomized Clinical Trial of Superiority, With Two Arms, Comparing Bariatric Surgery to the Recommended Medical Treatment for NASH (NASHSURG)	100	Mar 2025
NCT04506190	A Prospective Multicenter Study to Evaluate the Perioperative Outcomes of Laparoscopic and Robotic-Assisted Revisional Bariatric Surgery	100	Mar 2023 (active, not recruiting)
NCT04128995	Surgical or Medical Treatment for Pediatric Type 2 Diabetes	100	Dec 2025
NCT03236142	The Single, 300 cm Loop, Duodenal Switch (SIPS) Results in Less Nutritional Deficiencies Than the Standard Duodenal Switch (DS) Operation: A Multicenter, Randomized Controlled Trial	110	Jan 2025
NCT02692469	Laparoscopic single anastomosis- Duodenal-Jejunal Bypass With Sleeve Gastrectomy vs Laparoscopic Duodenal Switch as a Primary Bariatric Procedure. 5 Year Patient Follow	140	Apr 2026

NCT04165694	Single Anastomosis Duodenal Ileal Bypass (SADI) as a Second Stage for Sleeve Gastrectomy Weight Loss Failure	54	Dec 2030
NCT01172899	The BASIC Trial. Morbid Obesity in Children and Adolescents: a Prospective Randomised Trial of Conservative Treatment Versus Surgery	60	Dec 2022 (unknown status)

NCT: national clinical trial
[a] Denotes industry-sponsored or cosponsored trial

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinologists and American College of Endocrinology

In 2020, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published a comprehensive diabetes type 2 management algorithm.[132] Updates were made in 2022 and recommendations for bariatric surgery are presented in Table 10. [133]

Table 10. Recommendations for Bariatric Surgery in Diabetes

Recommendation	GOE	BEL
Persons with a BMI 35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), poorly controlled hypertension, NAFLD/NASH, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure	C	3
Persons with BMI 30 to 34.9 kg/m^2 and T2D with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure	B	2

BEL: best evidence level; BMI: body mass index; GOE: grade of evidence; NAFLD: nonalcoholic fatty liver disease; NASH: nonalcoholic steatohepatitis; OSA: obstructive sleep apnea; T2D: type 2 diabetes.

In 2016, AACE and ACE jointly published comprehensive clinical practice guidelines on medical care of patients with obesity.[134] The guidelines addressed 9 broad clinical questions with 123 recommendations. With regard to bariatric surgery for these guidelines, the following recommendations were added (Table 11).

Table 11. Recommendations for Bariatric Surgery Added in 2016

No.	Recommendation	GOE	BEL
35	Patients with obesity (BMI ≥30 kg/m^2) and diabetes who have failed to achieve targeted clinical outcomes following treatment with lifestyle therapy and weight-loss medications may be considered for bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion.	B	1[a]
121	"Patients with a BMI of ≥35 kg/m2 and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m^2 with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.		
	• BMI ≥35 kg/m^2 and therapeutic target of weight control and improved biochemical markers of CVD risk."	A	1
	• BMI >30 kg/m^2 and therapeutic target of weight control and improved biochemical markers of CVD risk.	B	2
	• BMI >30 kg/m^2 and therapeutic target of glycemic control in type 2 diabetes and improved biochemical marker of CVD risk."	C	3
122	"Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or CVD risk reduction alone."	D	NA
62	"Roux-en-Y gastric bypass should be considered as the bariatric surgery procedure of choice for patients with obesity and moderate to severe gastroesophageal reflux symptoms, hiatal hernia, esophagitis, or Barrett's esophagus."	Int	Int
	"Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux."	Strong	Strong

BEL: best evidence level; BMI: body mass index; CVD: cardiovascular disease; GOE: grade of evidence; In: intermediate.
[a] Downgraded due to evidence gaps.

American Academy of Clinical Endocrinologists, ACE, the Obesity Society, the American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists

In 2019, an update of the joint 2013 guidelines on support for bariatric surgery patients were published by AACE, the Obesity Society, and American Society for Metabolic and Bariatric Surgery (ASMBS) Obesity Medicine Association, and American Society of Anesthesiologists.[135] Recommendations on the following questions are summarized below.

"Which patients should be offered bariatric surgery?"

- "Patients with a BMI≥40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for a bariatric procedure."
- "Patients with a BMI≥35 kg/m^2 and 1 or more severe obesity-related complications remediable by weight loss, including T2D, high risk for T2D, poorly controlled hypertension, nonalcoholic fatty liver disease/nonalcoholic steatohepatitis, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure."
- "Patients with the following comorbidities and BMI≥35 kg/m2 may also be considered for a bariatric procedure, though the strength of evidence is more variable; obesity-hypoventilation syndrome and Pickwickian syndrome after a careful evaluation of

operative risk; idiopathic intracranial hypertension; GERD; severe venous stasis disease; impaired mobility due to obesity, and considerably impaired quality of life."

- "Patients with BMI of 30-34.9 kg/m^2 with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for a bariatric procedure; current evidence is insufficient to support recommending a bariatric procedure in the absence of obesity."
- "The BMI criterion for bariatric procedures should be adjusted for ethnicity (e.g., 18.5 to 22.9 kg/m2 is normal range, 23 to 24.9 kg/m2 overweight, and ≥25 kg/m2 obesity for Asians)."
- "Bariatric procedures should be considered to achieve optimal outcomes regarding health and quality of life when the amount of weight loss needed to prevent or treat clinically significant obesity-related complications cannot be obtained using only structured lifestyle change with medical therapy."

"Which bariatric surgical procedure should be offered?"

- "Selecting a bariatric procedure should be based on individualized goals of therapy (e.g., weight loss target and/or improvement in specific obesity-related complications), available local-regional expertise (obesity specialists, bariatric surgeon, and institution), patient preferences, personalized risk stratification, and other nuances as they become apparent. Notwithstanding technical surgical reasons, laparoscopic bariatric procedures should be preferred over open bariatric procedures due to lower early postoperative morbidity and mortality. Laparoscopic adjustable gastric banding, sleeve gastrectomy, RYGB, and LBPD/DS, or related procedures should be considered as primary bariatric and metabolic procedures performed inpatients requiring weight loss and/or amelioration of obesity-related complications. Physicians must exercise caution when recommending BPD, BPD with duodenal switch, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine. Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term(i.e., about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy."

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

In 2013, SAGES issued evidence-based guidelines for the management of hiatal hernia, which includes a recommendation about repair of hiatal hernias that are incidentally detected at the time of bariatric surgery.[126] These guidelines state, "During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired" (moderate quality evidence, weak recommendation).

In 2024, the SAGES issues updated guidelines for the surgical treatment of hiatal hernias.[136] Systematic reviews were conducted for four key questions regarding the treatment of HH in adults: surgical treatment of asymptomatic HH versus surveillance; use of mesh versus no mesh; performing a fundoplication versus no fundoplication; and RYGB versus redo fundoplication for recurrent HH. There was insufficient evidence to make evidence-based recommendations regarding surgical repair of asymptomatic HH or conversion to RYGB in recurrent HH, and therefore, only expert opinions were offered. The SAGES guidelines panel suggested that select asymptomatic patients may be offered surgical repair, with criteria outlined. Similarly, it suggested that conversion to RYGB for management of recurrent HH may be appropriate in certain patients and again described criteria. The evidence for the routine use of mesh in HH repair was equivocal and the panel deferred making a recommendation.

International Federation for the Surgery of Obesity and Metabolic Disorders
In 2019, members of societies affiliated with the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) established an expert consensus statement on revisional bariatric surgery (RBS).[137] Consensus agreement was established for the following recommendation statements:

- "RYGB is an acceptable RBS option after gastric banding."
- "OAGB is an acceptable RBS option after gastric banding."
- "SADI-S is an acceptable RBS option after gastric banding."[a]
- "RBS after gastric banding can be carried out in either 1 or 2-stage."
- "OAGB is an acceptable RBS option after SG."
- "BPD-DS is an acceptable RBS option after SG."
- "SADI-S is an acceptable RBS option after SG."
- "Prolongation of bilio-pancreatic limb is an acceptable RBS option after RYGB."
- "Prolongation of bilio-pancreatic limb is an acceptable RBS option after OAGB."[a]

BPD-DS: bilio-pancreatic diversion duodenal switch; OAGB: one anastomosis gastric bypass; RBS: revisional bariatric surgery; RYGB: Roux-en-Y gastric bypass; SADI: single anastomosis duodeno-ileal bypass with sleeve gastrectomy; SG: sleeve gastrectomy.
[a] Consensus achieved in second round of voting.

In 2020, members of societies affiliated with the IFSO established a position statement on Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS). [139] The following recommendations were made based on available data:

- "SADI-S/OADS offers substantial weight loss that is maintained into the medium term."
- "SADI-S/OADS provides an improvement in metabolic health that is maintained into the medium term."
- "Nutritional deficiencies are emerging as long-term safety concerns for the SADI-S/OADS procedure and patients undergoing this procedure need to be aware of this, and counseled to stay in long-term multidisciplinary care."
- "Surgeons performing the SADI-/OADS, as well as other bariatric/metabolic procedures, are encouraged to participate in a national or international registry so that data may be more effectively identified."
- "IFSO supports the SADI-S/OADS as a recognized bariatric/metabolic procedure, but highly encourages RCT's in the near future."

Guidelines for Children and Adolescents
Childerhose et al (2017) conducted a systematic review of adolescent bariatric surgery recommendation documents published in the United States and provided recommendations based on their review.[139] The literature search was conducted from 1999 through 2013 and identified 16 recommendations for inclusion: 10 clinical practice guidelines, 4 position statements, and 2 consensus statements. Fifteen of the 16 publications recommended

bariatric surgery for adolescents. The main reasons for recommending bariatric surgery for adolescents included: (1) surgery is effective in producing short- and long-term weight loss; (2) surgery is appropriate when the patient does not respond to behavioral or medical interventions; (3) surgery is appropriate when serious comorbidities threaten the health of the patient; and (4) surgery can improve long-term health and/or emotional problems. Body mass index thresholds ranged from 35 kg/m2 or more to 50 kg/m2 or more, with lower thresholds usually requiring the presence of at least 1 serious comorbidity. The minimum age was specified in 10 publications, with most using physiologic maturity (Tanner stage IV and/or 95% of adult height based on bone age, corresponding to ≥13 years for females and to ≥15 years for males) rather than years.

American Academy of Pediatrics

In 2019, the American Academy of Pediatrics (AAP) published a report outlining the current evidence regarding adolescent bariatric surgery that provided recommendations for practitioners and policy makers.[140] Within this report, AAP listed indications for adolescent metabolic and bariatric surgery that reflected 2018 ASMBS recommendations. Additionally, the AAP report noted that generally accepted contraindications to bariatric surgery included: "a medically correctable cause of obesity, untreated or poorly controlled substance abuse, concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes."

In 2023, the AAP published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages 2 to 18 years) with obesity.[141] The recommendations put forth in the guideline are based on evidence from RCTs and comparative effectiveness trials, along with high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is below:

- "Pediatricians and other PHCPs [pediatric health care providers] should offer referral for adolescents 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers (Grade C Evidence Quality)."

They list indications for adolescent metabolic and bariatric surgery (Table 12) that align with the 2019 indications.

Table 12. Indications for Adolescent Metabolic and Bariatric Surgery

Weight Criteria	Comorbid Conditions
Class 2 obesity; BMI ≥35, or 120% of the 95th percentile for age and sex, whichever is lower	Clinically significant disease, including, but not limited to, OSA (AHI >5), T2D, IIH, NASH, Blount disease, SCFE, GERD, depressed health-related quality of life, and hypertension
Class 3 obesity; BMI ≥40, or 140% of the 95th	Not required but commonly present

percentile for age and sex, whichever is lower	

AHI: apnea-hypopnea index; BMI: body mass index; GERD: gastroesophageal reflux disease; IIH: idiopathic intracranial hypertension; NASH: non-alcoholic steatohepatitis; OSA: obstructive sleep apnea; SCFE: slipped capital femoral epiphysis; T2D: type 2 diabetes.

American Society for Metabolic and Bariatric Surgery

In 2012, ASMBS best practice guidelines found that current evidence was insufficient to discriminate between specific bariatric procedures, but allowed that there is an increasing body of data showing safety and efficacy of Roux-en-Y gastric bypass and adjustable gastric band for the pediatric population.[142] Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:

Strong indications:

- Type 2 diabetes mellitus
- Moderate or severe obstructive sleep apnea (apnea-hypopnea index >15)
- Nonalcoholic steatohepatitis
- Pseudotumor cerebri

Less strong indications:

- Cardiovascular disease
- Metabolic syndrome

The guidelines stated that depression and eating disorders should not be considered exclusion criteria for bariatric surgery. The guidelines also noted that depression should be monitored following the procedure that eating disorders should be treated, and the patient stabilized prior to the procedure.

In 2018, ASBMS published an update to the 2012 guideline.[143] Summary of major changes in the guideline included:

- "Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents. Long-term outcomes of GERD after vertical sleeve gastrectomy are still not well understood."
- "There are no data that the number of preoperative weight loss attempts correlated with success after metabolic/bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after metabolic/bariatric surgery but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity."
- "The use of the most up to date definitions of childhood obesity are as follows: (1) BMI cut offs of 35 kg/m2 or120% of the 95th percentile with a comorbidity, or (2) BMI >40 kg/m2 or 140% of the 95th percentile without a comorbidity (whichever is less). Requiring adolescents with a BMI >40 to have a comorbidity (as in the old guidelines) puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (ata BMI <45 kg/m2) can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end organ damage from comorbidities."

- "Certain comorbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, GERD, and cardiac risk factors. Given the poor outcomes of medical therapies for T2D in children, these comorbidities may be considered an indication for metabolic/bariatric surgery in younger adolescents or those with lower obesity percentiles."
- "Vitamin B deficiencies, especially B1 appear to be more common in adolescents both preoperatively and postoperatively; they should be screened for and treated. Prophylactic B1 for the first 6 months postoperatively is recommended as is education of patients and primary care providers on the signs and symptoms of common deficiencies."
- "Developmental delay, autism spectrum, or syndromic obesity should not be a contraindication to metabolic/bariatric surgery. Each patient and caregiver team will need to be assessed for the ability to make dietary and lifestyle changes required for surgery. Multidisciplinary teams should agree on the specific needs and abilities of the given patient and caregiver and these should be considered on a case-by-case basis with the assistance of the hospital ethics committee where appropriate."
- "Because metabolic/bariatric surgery results in better weight loss and resolution of comorbidities in adolescents at lower BMI's with fewer comorbidities, referrals should occur early, as soon as a child is recognized to suffer from severe obesity disease (BMI >120% of the 95th percentile or BMI of 35). Prior weight loss attempts, Tanner stage, and bone age should not be considered when referring patients to a metabolic/bariatric surgery program."
- "Unstable family environments, eating disorders, mental illness, or prior trauma should not be considered contraindications for metabolic/bariatric surgery in adolescents; however, these should be optimized and treated where possible before and surrounding any surgical intervention for obesity."

In 2020, the ASMBS endorsed SADI-S for the primary treatment of obesity or metabolic disease: [144]

- SADI-S, a modification of classic Roux-en-Y DS, is therefore endorsed by ASMBS as an appropriate metabolic bariatric surgical procedure.
- Publication of long-term safety and efficacy outcomes is still needed and is strongly encouraged, particularly with published details on SG size and common channel length.
- Data for these procedures from accredited centers should be reported to the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database and separately recorded as single-anastomosis DS procedures to allow for accurate data collection.
- There remain concerns about intestinal adaptation, nutritional issues, optimal limb lengths, and long-term weight loss/regain after this procedure. As such, ASMBS recommends a cautious approach to the adoption of this procedure, with attention to ASMBS-published guidelines on nutritional and metabolic support of bariatric patients, in particular for DS patient.

In 2022, the ASMBS updated their guideline on indications for metabolic and bariatric surgery. [145] They noted that prospective data demonstrated durable weight loss and maintained co-morbidity remission in patients as young as 5 years of age. Additionally, the ASMBS stated that metabolic and bariatric surgery do not negatively impact pubertal development or linear growth, and therefore a specific Tanner stage and bone age should not be considered a requirement for surgery. Other statements supported 2018 recommendations, including that

syndromic obesity, developmental delay, autism spectrum, or a history of trauma would not be considered a contraindication to bariatric surgery in children or adolescents. The ASMBS's recommendation related to bariatric surgery in adolescents is below:

- MBS is recommended for individuals with BMI ≥35 kg/ m2, regardless of presence, absence, or severity of comorbidities.
- MBS is recommended in patients with T2D and BMI ≥30 kg/m2.
- MBS should be considered in individuals with BMI of 30-34.9 kg/m2 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.
- Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m2 Access to MBS should not be denied solely based on traditional BMI risk zones.
- There is no upper patient-age limit to MBS. Older individuals who could benefit from MBS should be considered for surgery after careful assessment of co-morbidities and frailty.
- Carefully selected individuals considered higher risk for general surgery may benefit from MBS.
- MBS is an effective treatment of clinically severe obesity in patients who need other specialty surgery, such as joint arthroplasty, abdominal wall hernia repair, or organ transplantation.
- Consultation with a multidisciplinary team can help manage the patient's modifiable risk factors with a goal of reducing risk of perioperative complications and improving outcomes. The ultimate decision for surgical readiness should be determined by the surgeon.
- Severe obesity is a chronic disease requiring long-term management after primary MBS. This may include revisional surgery or other adjuvant therapy to achieve desired treatment effect.
- Children and adolescents with BMI. >120% of the 95th percentile and a major co-morbidity, or a BMI >140% of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center.

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE) 2014 (updated 2023) guideline:[151]

- The guidelines suggests that the Asian population is at an increased risk of chronic health conditions at a lower BMI than people from a white family background. Therefore class 1 obesity is defined at a BMI ≥ 25 kg/m2.
- Additionally, the guideline suggests consideration for reducing the BMI threshold for surgical intervention by 2.5 kg/m2 in the Asian population to account for the fact that these groups are prone to central adiposity and their cardiometabolic risk occurs at a lower BMI.

Endocrine Society

The Endocrine Society published recommendations for the following for prevention and treatment of pediatric obesity in 2008.[146] In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology.[147] These guidelines recommended the following:

"We suggest that bariatric surgery be considered only under the following conditions:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI above 40kg/m^2 or has BMI above 35 kg/m^2 and significant, severe comorbidities.
- Extreme obesity and comorbidities persist, despite compliance with a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a medical center employing a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

We recommend against bariatric surgery for preadolescent children, for pregnant or breast-feeding adolescents (and those planning to become pregnant within 2 yr of surgery) and in any patient who has not mastered the principles of healthy dietary and activity habits and/or has an unresolved substance abuse, eating disorder, or untreated psychiatric disorder."

Guidelines for Esophagogastroduodenoscopy

American Society for Metabolic and Bariatric Surgery

In 2021, the ASMBS issued a position statement addressing the need and strategies for preoperative endoscopic screening and postoperative surveillance for mucosal abnormalities in patients undergoing bariatric surgery, specifically for patients undergoing SG and RYGB.[131] The statement, based on current clinical knowledge and expert opinion, also notes that the general principles may apply to other procedures like BPD and BPD with DS, though there is paucity of procedure-specific literature. The ASMBS emphasizes that this statement does not establish a standard of care and will be updated as new evidence emerges. The ASMBS provided the following summary:

Table 13. Summary of ASMBS Recommendations for Upper Gastrointestinal Endoscopy

Upper Gastrointestinal Endoscopy Before Bariatric Surgery	**Upper Gastrointestinal Endoscopy After Bariatric Surgery**
Clinical evaluation by symptoms alone does not reliably diagnose or rule out GERD, and upper gastrointestinal abnormalities are found in a significant proportion of patients undergoing EGD before bariatric surgery, even in asymptomatic patients. While some of these findings do not modify medical or surgical management, routine preoperative EGD is justifiable and should be done at the surgeon's discretion.	After bariatric surgery, screening with EGD should be considered for all patients with gastrointestinal symptoms, including GERD symptoms. It is reasonable to perform EGD on patients ≥3 years after SG, irrespective of GERD symptoms, to rule out Barrett's esophagus. More long-term surveillance every 5 years after that would be reasonable even if the index screening EGD is normal and is compatible with clinicians exercising an abundance of caution until better-designed and longer term studies are available.

EGD: Esophagogastroduodenoscopy; GERD: gastroesophageal reflux disease; SG: sleeve gastrectomy.

American Gastroenterological Association

In 2024, the American Gastroenterological Association published a practice update on performing high-quality upper endoscopy.[148] The best practice statements include confirming an appropriate indication for EGD, ensuring adequate visualization with mucosal cleansing and insufflation, and using a high-definition white-light endoscopy system. The guidance also

endorses careful gastric mucosal inspection in anterograde and retroflexed views and documenting abnormalities using established classifications and standard terminology, whenever possible.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Government Regulations
National:

NCD 100.1 Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity
Effective December 17, 2013:
http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Michigan&KeyWord=bariatric&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=100.1&ncd_version=3&basket=ncd%25253A100%25252E1%25253A3%25253ABariatric+Surgery+for+Treatment+of+Morbid+Obesity&bc=gAAAABAAAAAAAA%3d%3d&

Nationally Covered Indications
Effective for services performed on and after February 21, 2006, Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.[150]

Effective for dates of service on and *after* February 21, 2006, these procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006).

Effective for dates of service on and after September 24, 2013, facilities are no longer required to be certified.

Effective for services performed on and after February 12, 2009, the Centers for Medicare & Medicaid Services (CMS) determines that Type 2 diabetes mellitus is co-morbidity for purposes of this NCD.

Nationally Non-Covered Indications
Treatments for obesity alone remain non-covered.
Supplemented fasting is not covered under the Medicare program as a general treatment for obesity (see section D. below for discretionary local coverage).

The following bariatric surgery procedures are non-covered for all Medicare beneficiaries:
- **Open** adjustable gastric banding;
- **Open** sleeve gastrectomy;

- Laparoscopic sleeve gastrectomy (**prior to June 27, 2012**);
- Open and laparoscopic vertical banded gastroplasty;
- Intestinal bypass surgery; and,
- Gastric balloon for treatment of obesity.

Effective for services performed on and after June 27, 2012, Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a.-c. are satisfied:
a. The beneficiary has a body-mass index (BMI) ≥ 35 kg/m^2,
b. The beneficiary has at least one co-morbidity related to obesity, and,
c. The beneficiary has been previously unsuccessful with medical treatment for obesity.

The determination of coverage for any bariatric surgery procedures that are not specifically identified in an NCD as covered or non-covered, for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity, is left to the local MACs.

Where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes, or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient is eligible for coverage on a case-by-case basis or pursuant to a local coverage determination. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

Local:
There is no current WPS LCD on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Gastric Electrical Stimulation
Vagus Nerve Blocking for Morbid Obesity (Retired 7/1/21)

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150. United States Census Bureau. The Asian population: 2010. March 2012.
151. National Institute for Health and Care Excellence (NICE). NICE guidelines [CG189]. Obesity: identification, assessment and management. November 2014. Updated January 2023.
152. Centers for Medicare and Medicaid Services (CMS). Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (CAG-00250R). 2006; https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=160.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/22/02	5/22/02	5/22/02	Joint medical policy established
9/11/02	9/11/02	9/11/02	New procedure added
11/20/02	11/20/02	12/05/02	Criteria updated
2/9/04	2/9/04	3/1/04	Criteria updated maintenance review
5/5/04	5/5/04	6/1/04	Coding update S2085 which was effective 01/01/04 but was already payable with PC 43659 until 12/31/03
6/15/05	6/15/05	6/10/05	Maintenance review, coding update
10/24/05	10/24/05	10/24/05	New codes added for effective 1/1/06
7/1/06	5/5/06	6/28/06	Routine maintenance
7/1/07	N/A	6/24/07	Routine maintenance
1/1/08 – BCBSM 9/1/07 - BCN	10/16/07	11/12/07	Maintenance review new procedure added
11/1/08	8/19/08	10/30/08	Maintenance review new procedure added
7/1/09	4/21/09	4/20/09	Maintenance review
11/1/10	8/17/10	10/13/10	Re-presented at committee with addition of sleeve gastrectomy as established as a standard, stand-alone gastric surgical weight reduction procedure. Added CPT code for sleeve gastrectomy (43775).
5/1/12	2/21/12	2/21/12	Revised BCN benefit page. Title changed from “Gastric Surgery for Morbid Obesity” to “Bariatric Surgery (Gastric Surgery for Morbid Obesity).
5/1/13	2/19/13	2/19/13	Updated NCD and LCD to include coverage for sleeve gastrectomy for Medicare members. Updated policy to include discussion on bariatric surgery for adolescents. Updated references.

1/1/14	10/15/13	10/25/13	Clarified language regarding repeat bariatric surgery: non-compliance vs. complications. Updated references and rationale. Added new Medicare decision memo information.
5/14/14	N/A	N/A	Deleted vertical banded gastroplasty, 43842, as an exclusionary criterion. It was originally added in error.
5/1/15	2/17/15	2/27/15	Routine maintenance. Added information regarding endoluminal bariatric procedures as experimental/investigational. Added references. No change in policy status.
7/1/16	4/19/16	4/19/16	Routine maintenance. Added single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) to the exclusions. Added word “trials” under SADI-S description, pg. 24.
3/1/17	12/13/16	12/13/16	Routine policy maintenance.
1/1/18			• Updated literature review focused on surgery in patients with type 2 diabetes and lower BMI February 9, 2017 • multiple references added (33, 36, 38, 65, 67, 68, 71, 74 and 75) • Intragastric balloon, aspiration therapy and bariatric surgery in preadolescents added to exclusions
7/1/18	4/17/18	4/17/18	• Updated rationale section, added the following references: 11, 36, 38, 47, 50, 62, 69-70, 73, 79, 112, 116, 119, 139-141. Added the SIPS procedure to the policy as E/I. No change in policy status.
7/1/19	4/16/19		Routine policy maintenance, updated rationale, added references 38, 44, 45, 89, and 119. Deleted expired codes 96101-96103 and replaced with codes 96130-96139, code 96146 is E/I.

7/1/20	4/14/20		Routine policy maintenance, updated rationale, added references 15, 40, 50, 97, 107 and 148. No change in policy status.
7/1/21	4/20/21		Routine policy maintenance, added references 36, 154-170, added Natural orifice Transluminal Endoscopic Surgery (Notes ™) under exclusion. No change in policy status. Updated the policy to say 4 years for both BCBSM and BCN as per the JUMP's recommendation and eliminated the 6 months waiting period statements. The below is the updated language added to the policy. • The patient has undergone multidisciplinary evaluation by an established bariatric treatment program to include medical, nutritional and mental health evaluations to determine ultimate candidacy for bariatric surgery. Such an evaluation should include an assessment of the patient's likely ability and willingness to cooperate effectively with a rigorous post-operative program. This should include documentation of past participation in a non-surgical weight loss program. • The non-surgical program participation and multi-disciplinary evaluation must have occurred within 4 years of the date of surgery. Eliminated all but one paragraph in the rationale on VBG, enough to say it has been abandoned. Removed the 43842 from covered/EST to Excluded. Added in the Am. Acad. Peds criteria to inclusions because although they are virtually identical to adult criteria they include the % above expected

			on the growth chart as an alternative to BMI.
7/1/22	4/19/22		• Routine policy maintenance • References added and updated. • No change in policy status • Added for clarification purposes under Inclusion: Documentation of a non-surgical weight loss program is waived for super morbidly obese individuals who have a BMI ≥50. This was removed inadvertently last year when the decision to remove the six full consecutive months documentation.
7/1/23	4/26/23		• Routine policy maintenance • References added and updated. • Added Overstitch device under Exclusions and under section Endoscopic Revision Procedures – ▪ Endoscopic/endoluminal procedures (including but not limited to insertion of the StomaphyX™ device, use of the Overstitch device, insertion of a gastric balloon, endoscopic gastroplasty, or use of an endoscopically placed duodenojejunal sleeve) as a primary bariatric procedure or as a revision procedure, (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches). • This policy will replace the IMP policy " Use of Overstitch Device for endoscopic gastrogastric fistula closure and for

			endoscopic closure of duodenal diverticula” • Added codes 43290 Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon and 43291 Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s) under E/I per code update. JUMP policy already has Intragastric balloons under Exclusions and policy evidence already support Intragastric balloons as E/I. • New this review from BCBSA – BCBSA adopted the CDC’s classification of obesity. Updated morbid obesity to class III obesity as per BCBSA. ▪ Per the Centers for Disease Control and Prevention (CDC), obesity is also frequently classified into the categories of Class 1: BMI of 30 to < 35 kg/m2; Class 2: BMI of 35 to< 40 kg/m2; and Class 3: BMI of 40 kg/m2 or higher. Class 3 obesity is sometimes categorized as “severe” obesity. • Vendor: N/A • Added Two-stage bariatric surgery procedures (e.g., SG as initial procedure followed by BPD at a later time) under exclusion to align with BCBSA, There is already a PICO section to support this procedure as an exclusion in the policy. • Updated under Exclusions **from** Any bariatric surgery for patients with type 2 diabetes who have a BMI of less than 35 **to** Any bariatric surgery for individuals

			with type 2 diabetes who have a BMI of less than 30. Post JUMP changes: • Added “with duodenal switch” to the Medical Policy Statement (MPS). • Removed type 2 diabetes from under: a BMI of >35 with one or more co-morbid conditions including, but not limited to under Inclusions. • Added a BMI > 30 with type 2 diabetes under Inclusions. • Moved intragastric balloons and aspiration therapy device from being separate bullets to under the Endoscopic/endoluminal procedures bullet under Exclusions. • Rearranged Types of Bariatric Surgery Procedures section with the most common types of bariatric surgery first: Roux-en-Y gastric bypass, sleeve gastrectomy, and Biliopancreatic diversion with duodenal switch. • Rearranged MPS reordering the options to match their above order, to read: The safety and effectiveness of laparoscopic and open gastric restrictive procedures including but not limited to Roux-en-Y gastric bypass, sleeve gastrectomy, biliopancreatic diversion with duodenal switch, and adjustable gastric band have been established. They may be considered useful therapeutic options when specified criteria are met. (ky)
7/1/24	4/16/24		• Routine maintenance • BCBSA has not yet reviewed policy 7.01. 47 – Bariatric Surgery, including addition of indications relating to treatment

			of primary or postoperative GERD (April, 2024 MPP). • Added codes C9784 and C9785 effective 7/1/23 per code update under E/I. Added code 0813T effective 1/1/24 per code update under E/I. • For clarification purposes only: separated the below criteria under Inclusions to make it clearer that the BMI of 40 or more is a stand-alone and no other criteria need to be met. The individual has a: ▪ A BMI of ≥ 40 kg/m2 (class III) OR ▪ A BMI of ≥35 to 39.9 kg/m2 (class II) with one or more co-morbid conditions including, but not limited to: Vendor: N/A (ky)
7/1/25	4/21/25		• Routine Maintenance • Updated Inclusions and Exclusion sections, accordingly. • An investigational statement concerning the routine use of esophagogastroduodenoscopy (EGD) during bariatric surgery added under the Exclusion section. This is in alignment with BCBSA. A new PICO, as well as indications and evidence review for EGD in the context of bariatric surgery was added. • The SADI-S and SIPS procedures are added to the MPS. These 2 procedures were removed from the Exclusions section. This will be a divergent from BCBSA. • Removed SADI-S and SIPS from code 43999 under E/I and added them to this code under EST. • Revisions have been made to the Rationale section; references added/updated.

			• Vendor: N/A (ky).

Next Review Date: 2nd Qtr. 2026

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 10/1/97	Revised: 5/8/01, 11/1/01
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BARIATRIC SURGERY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, see certificate for applicable deductibles and co-payments. **Note: Gastric surgery is not a covered benefit under SRO Tier 2**
Self-funded Groups: **U-M Premier Care** **Grad Care**	Refer to the weight reduction section of the certificate for deductibles and copayments.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.